UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, STATE OF CALIFORNIA, COMMONWEALTH OF MASSACHUSETTS, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF MAINE, STATE OF MARYLAND, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NORTH CAROLINA, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, and STATE OF WISCONSIN, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*, and ROGER SEVERINO, *in his official capacity as Director of the Office for Civil Rights at the United States Department of Health and Human Services*, Defendants.	Civil Action No. 1:20-cv-5583-AKH

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

In 2010, Congress enacted the Patient Protection and Affordable Care Act ("ACA"), a comprehensive set of health care reforms to expand access to quality, affordable care in the United States. The ACA contains a landmark civil rights provision, Section 1557, 42 U.S.C. § 18116 ("Section 1557"), which prohibits discrimination by federally-funded health care providers and health insurers based on race, color, national origin, sex, age, and disability, and became the first federal law to prohibit sex-based discrimination in the health context. In 2016, Defendant U.S. Department of Health and Human Services ("HHS" or the "Department") promulgated a rule implementing Section 1557, 81 Fed. Reg. 31,376 (May 18, 2016) (formerly codified at 45 C.F.R. pt. 92) ("2016 Rule"). On June 19, 2020, HHS published a new rule, 85 Fed. Reg. 37,160 (June 19, 2020) ("2020 Rule" or "Rule"), rescinding most of the 2016 Rule's core provisions and amended other HHS regulations unrelated to Section 1557.

On July 20, 2020, Plaintiffs—22 states and the District of Columbia (the "States")—filed this action against HHS, Secretary Alex Azar, and HHS Office for Civil Rights ("OCR") Director Roger Severino to challenge the 2020 Rule's rescission of critical federal civil rights protections for the vulnerable populations protected by Section 1557 because it violates the Administrative Procedure Act ("APA), 5 U.S.C. § 706(2)(A), (C), and the Fifth Amendment's equal protection guarantees. Compl. ¶ 15 [ECF No. 1]. Specifically, Plaintiffs challenge the Rule's (1) exclusion of health insurance companies and many of HHS's own programs from the Rule's scope; (2) elimination of express federal protections for transgender individuals based on the erroneous interpretation that Section 1557 affords that community no such protections; (3) removal of protections against sexual orientation and gender identity discrimination from unrelated Center for Medicare and Medicaid Services ("CMS") regulations; (4) incorporation of

the broad religious exemption and "abortion neutrality" provision from Title IX of the Education Amendments of 1972 ("Title IX"), to permit religiously-affiliated health providers to deny care to LGBTQ people, persons seeking or who have obtained reproductive health care, or others; and (5) elimination of critical requirements intended to ensure that limited English proficient ("LEP") individuals have meaningful access to health care. These changes are all at odds with the central purpose of the ACA to increase access to quality, affordable health care and to eradicate arbitrary barriers to such access, including discrimination. *See King v. Burwell*, 576 U.S. 473, 478 (2015).

Plaintiffs now move for partial summary judgment on their claims under the APA that the Rule is arbitrary, capricious, contrary to law, and in excess of HHS's statutory jurisdiction. 5 U.S.C. § 706(2)(A), (C). Plaintiffs are entitled to this relief for the following reasons:

1. Plaintiffs have standing to challenge the 2020 Rule because it has harmed their sovereign, quasi-sovereign, economic, and proprietary interests, and will continue to cause injury to these interests unless and until it is vacated.

2. The 2020 Rule is contrary to law, in violation of the APA, 5 U.S.C. § 706(2)(A), because it: (a) violates the plain text of Section 1557 by excluding private health insurance companies and many HHS programs and activities from the Rule's scope; (b) violates Section 1557's prohibition on discrimination "on the basis of sex" by eliminating express protections for transgender people based on the legally unsound position that federal civil rights statutes prohibiting discrimination on the basis of sex, including Section 1557, do not prohibit discrimination against LGBTQ people—a view that is flatly irreconcilable with the Supreme Court's recent decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020); and (c) eliminates prohibitions on sexual orientation and gender identity discrimination from unrelated CMS regulations based on that same erroneous legal interpretation.

3. The Rule's incorporation of the broad religious exemption and "abortion neutrality" provision of Title IX of the Education Amendments of 1972 exceeds HHS's statutory authority, in violation of the APA, 5 U.S.C. § 706(2)(C), because Section 1557 contains no such exemptions, and neither Section 1557 nor the ACA authorizes HHS to incorporate new exemptions that will have the effect of denying health care to many individuals.

4. The Rule is arbitrary and capricious, in violation of the APA, 5 U.S.C. § 706(2)(A), because (a) the Rule's rescission of the definition of "on the basis of sex" and express protections for transgender people was based solely on HHS's incorrect interpretation of Title IX, was made without any consideration to the Supreme Court's *Bostock* decision, failed to account for failed to account for the harms to individuals and the public health resulting from those policy reversals, and otherwise has no valid legal or factual basis; (b) the Rule's elimination of essential requirements that covered entities provide language assistance services to LEP persons to ensure meaningful access to care conflicts with Section 1557's purpose, is contrary to the evidence of the necessity of those requirements, and did not account for the harms to those unable to obtain care without those services; (c) incorporates Title IX's religious exemption and "abortion neutrality" provisions without regard to the health ramifications to result from these exemptions; and (d) is based on a cost-benefit analysis that wholly ignores the harms to individuals, the public health, or the costs to state and local governments arising from delayed or denied care resulting from the Rule's changes.

Plaintiffs therefore respectfully request that the Court vacate and set aside the 2020 Rule.

BACKGROUND

The 2020 Rule substantially amends HHS's regulations implementing Section 1557 of the ACA, 42 U.S.C. § 18116, a federal civil rights law that expressly prohibits discrimination on

the basis of race, color, national origin, sex, disability, and age in health programs and activities receiving federal financial assistance and federal agencies administering health programs. 85 Fed. Reg. at 37,244-47 (codified at 45 C.F.R. §§ 92.1-92.105). It also amends HHS's Title IX regulations, *id.* at 37,243-44 (codified at 45 C.F.R. §§ 86.18, 86.31, 86.71), and several CMS regulations governing managed care programs, *id.* at 37,243, 37,247-48 (codified at 42 C.F.R. §§ 438.3, 438.206, 440.262, 460.98, 460.112, 147.104, 155.120, 155.220, 156.200, 156.1230), none of which relate to Section 1557. The 2020 Rule reverses much of HHS's earlier Section 1557 policy, including removing critical nondiscrimination protections for transgender and gender nonconforming individuals, persons seeking reproductive health care or with pregnancy-related conditions, LEP individuals, and all persons facing discrimination by certain heath insurers and HHS programs that the Rule now excludes from its ambit.

I. OVERVIEW OF SECTION 1557

Section 1557, enacted in 2010 as part of the ACA, prohibits discrimination in health programs and activities that receive federal financial assistance or are administered by federal agencies. 42 U.S.C. § 18116(a). Under the statute,

> an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.) ["Title VI"], title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq*.) ["Title IX"], the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq*.) ["Age Discrimination Act"], or section 794 of title 29 ["Section 504"],[1] be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violation of this subsection.

[1] 29 U.S.C. § 794 codifies Section 504 of the Rehabilitation Act of 1973 ("Section 504").

Id. By incorporating the protected classifications and enforcement mechanisms under Title VI, Title IX, the Age Discrimination Act, and Section 504 (collectively, the "Civil Rights Statutes"), Section 1557 prohibits discrimination in health programs on the basis of race, color, national origin, sex, age, and disability, which may be enforced by the administrative and judicial enforcement mechanisms available under those laws. *Id.* Section 1557 authorizes the Secretary of HHS to "promulgate regulations to implement this section." *Id.* § 18116(c).

HHS's OCR began accepting and investigating complaints of discrimination after the ACA was enacted in 2010. This included investigating sex discrimination complaints from transgender individuals. *See* 81 Fed. Reg. at 31,387 & n.57; 85 Fed. Reg. at 37,191. HHS's post-ACA enforcement efforts were consistent with the its finding that "[i]ndividuals, families and communities that have systematically experienced social and economic disadvantage face greater obstacles to optimal health," and that "[c]haracteristics such as . . . gender, . . . , sexual orientation or gender identity, . . . or other characteristics historically linked to exclusion or discrimination are known to influence health status."[2]

II. THE 2016 RULE

The 2016 Rule, published on May 18, 2016, was HHS's first rule implementing Section 1557. The 2016 Rule was the culmination of a three-year rulemaking process that included a 2013 request for information, 78 Fed. Reg. 46,558 (Aug. 1, 2013) ("2013 RFI"), and a 2015 notice of proposed rulemaking, 80 Fed. Reg. 54,172 (Sept. 8, 2015) ("2015 NPRM"). HHS received more than 25,000 comments in response to these proposals, many documenting widespread discrimination in the health care system, including by medical providers and health insurers. 80 Fed. Reg. at 54,172; 81 Fed. Reg. at 31,376. In promulgating the 2016 Rule, HHS

[2] *See* Ex. 1, at 2 (HHS, *HHS Action Plan to Reduce Racial and Ethnic Health Disparities* (2011)).

found that, based on its enforcement experience, a prescriptive regulation was necessary to "promote understanding of and compliance with Section 1557 by covered entities and the ability of individuals to assert and protect their rights under the law," in furtherance of the ACA's central aim of promoting health care access by, among other things, combating discrimination that "can often lead to poor and inadequate health care or health insurance or other coverage . . . and exacerbate existing health disparities in underserved communities," and that individuals facing discrimination often avoid seeking care, resulting in adverse public health outcomes and higher medical costs associated with that delayed or denied care. 81 Fed. Reg. at 31,444.

A. The 2016 Rule Was Predicated on HHS's Extensive Factual Findings Showing Widespread Discrimination in the Health Care System.

The 2016 Rule cited substantial evidence of widespread health discrimination and related harms to individuals and the public. *Id.* at 31,459-61. For example, the 2016 Rule cited data showing that transgender people face widespread bias-motivated refusals of care by providers and barriers to adequate insurance coverage, including categorical exclusions of gender affirming care. *Id.* at 31,460-61. HHS found that such barriers lead to delayed or denied care for transgender individuals, with resulting harms to individuals and the public health. *Id.* With respect to LEP individuals, the Rule found that the lack of reliable language assistance services is a major barrier to health care access and impedes providers' ability to provide competent care. *Id.* at 31,459. Based on these findings, HHS projected that enforcing Section 1557 through the 2016 Rule would increase access to care, reduce health disparities, and reduce public health costs, among other benefits. *Id.* at 31,460-61.

B. The 2016 Rule Detailed Section 1557's Broad Application to Health Programs and Activities That Receive Federal Financial Assistance or Are Administered by Federal Agencies.

The 2016 Rule specified that Section 1557 broadly applies to all health programs and activities receiving federal financial assistance or that are administered by federal agencies, including health providers and insurers, *id.* at 31,467 (former § 92.4). In accordance with the statute's plain language, the rule defined a "covered entity" as "(1) [a]n entity that operates a health program or activity, any part of which receives Federal financial assistance; (2) [a]n entity established under Title I of the ACA that administers a health program or activity; and (3) [t]he Department." *Id.* at 31,466 (former § 92.4). It defined "health program or activity" as "the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage." *Id.* at 31,467 (former § 92.4).

C. The 2016 Rule Clarified the Scope of Section 1557's Prohibitions on Discrimination Based on Sex.

Consistent with relevant federal case law, the 2016 Rule expressly defined discrimination "on the basis of sex" to include, "discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity." *Id.* (former § 92.4); *see also id.* at 31,384-85, 31,387-88.[3] Based on factual findings on common forms of discrimination faced by transgender people in health settings, the 2016 Rule contained provisions specifying prohibited conduct against

[3] Although the 2016 Rule stopped short of expressly prohibiting sexual orientation discrimination as a form of sex discrimination, it noted the rapidly evolving case law on that issue, and observed that, at minimum, any LGBTQ person facing discrimination based on nonconformity to sex stereotypes would be protected. *Id*. at 31,388-90. Accordingly, HHS noted that OCR would "evaluate complaints alleging sex discrimination related to an individual's sexual orientation to determine whether they can be addressed under Section 1557." *Id.* at 31,390.

transgender people that is unlawful sex-based discrimination under Section 1557. *Id.* at 31,471-72 (former §§ 96.206-207). The 2016 Rule required that each covered entity treat transgender people consistent with their gender identity, except that the entity may not deny traditionally sex-specific services to a transgender person because of the person's transgender status;[4] expressly prohibited health insurers from denying or limiting coverage to transgender individuals because of their transgender status; and further prohibited insurers from maintaining categorical coverage exclusions of health services related to a gender transition. *Id.* at 31,471-72 (former § 92.206).

D. The 2016 Rule required covered entities to ensure nondiscriminatory access to health services for individuals with limited English proficiency.

The 2016 Rule also established prescriptive language access requirements to ensure nondiscriminatory access to health services for LEP individuals. *Id.* at 31,410-11 (former § 92.201). Consistent with HHS's factual findings and applicable Title VI case law regarding national origin discrimination, the 2016 Rule directed covered entities to "take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered in its health programs and activities." *Id.* at 31,470-71 (former § 92.201). The 2016 Rule noted "that the provision of language assistance services is essential to ensure the equality of opportunity promised by nondiscrimination laws" prohibiting national origin discrimination, because LEP persons' "lack of proficiency in English—and the use of non-English language—is a direct outgrowth of, and is integrally tied to, their national origins." *Id.* at 31,410 (citing *Lau v. Nichols*, 414 U.S. 563, 566 (1974)). The 2016 Rule specified that language assistance services must be provided at no cost and set forth certain minimum requirements for interpretation and translation services. *Id.* at 31,470 (former § 92.201(c)-(f)).

[4] For example, the 2016 Rule noted that "a covered entity may not deny, based on an individual's identification as a transgender male, treatment for ovarian cancer where the treatment is medically indicated." 81 Fed. Reg. at 31,428.

Separately, the 2016 Rule required covered entities to take appropriate and ongoing steps to notify beneficiaries, enrollees, applicants, and the public of their Section 1557-compliant nondiscrimination policies. *Id.* at 31,469 (former § 92.8). To that end, the rule instructed covered entities to post translated nondiscrimination notices and "taglines" (i.e., short 1-2 sentence descriptions on how to access language assistance services) on entities' websites, significant communications, and in conspicuous physical locations, to inform LEP persons of their rights and the availability of language assistance services. *Id.*

E. The *Franciscan Alliance* Lawsuit

On December 31, 2016, a federal court in Texas preliminarily enjoined HHS from enforcing the portions of the 2016 Rule's definition of "on the basis of sex" that referred to "gender identity" and "termination of pregnancy." *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 695 (N.D. Tex. 2016). Following the change in presidential administrations in January 2017, HHS did not appeal that ruling. *See Walker v. Azar*, --- F. Supp. 3d ----, 2020 WL 4749859, at *2 (E.D.N.Y. Aug. 17, 2020). In October 2019, that court vacated the 2016 Rule insofar as the definition of "on the basis of sex" included those two terms. *Franciscan All. v. Azar*, 414 F. Supp. 3d 928, 945 (N.D. Tex. 2019), *modified by* Order Modifying Final Judgment (N.D. Tex. Nov. 21, 2019) [Ex. 2], *appeal filed*, No. 20-10093 (5th Cir. Jan. 24, 2020).[5] The court did not enter a permanent injunction, nor did it vacate any other part of the 2016 Rule. Thus, the portions of the definition of "on the basis of sex" that included "pregnancy, false pregnancy, . . . childbirth or related medical conditions, [and] sex stereotyping" in the former § 92.4, as well as the specific prohibitions on discrimination against transgender people contained in the former §§ 92.206-207, were unaffected by *Franciscan Alliance*.

[5] That appeal is pending. *See* Ex. 3 (Letter from Lyle W. Cayce to Luke William Goodrich (Aug. 11, 2020)).

III. HHS'S PROMULGATION OF THE 2020 RULE

A. In Its 2019 Notice of Proposed Rulemaking, HHS Proposed a Wholesale Abandonment of the 2016 Rule's Core Provisions.

Less than three years after the 2016 Rule went into effect, HHS issued a Notice of Proposed Rulemaking, Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846 (June 14, 2019) ("2019 NPRM"). The 2019 NPRM proposed, in relevant part, eliminating the definition of "on the basis of sex," stripping the express protections for transgender people, reducing protections for LEP individuals, and excluding many private health insurance plans, the Federal Employee Health Benefits ("FEHB") program, Medicare Part B plans, and many health programs and activities administered by HHS from the scope of Section 1557's protections. 84 Fed. Reg. at 27,850-51, 27,856-57, 27,860, 27, 863, 27,865, 27,868, 27,869-70, 27,870-71, 27,883-84. The 2019 NPRM also proposed "conforming" amendments to HHS's Title IX regulations and removing prohibitions against sexual orientation and gender identity discrimination from several unrelated CMS regulations. *Id.* at 27,869-71.

During the notice and comment period, HHS received 198,845 comments from individuals, civil rights groups, medical and public health organizations, scholars, members of Congress, state and local agencies, health providers, individuals, and others.[6] 85 Fed. Reg. at 37,164. Commenters expressed significant opposition to the proposed changes, including concerns about the proposed rule's inconsistency with governing law and federal cases interpreting Section 1557; confusion among individuals, providers, and insurers about patients' rights; and harms to transgender people, LEP individuals, and others resulting from reduced protections; among other concerns. *Id.* at 37,164-222.

[6] The 2019 NPRM docket is available at https://www.regulations.gov/docket?D=HHS-OCR-2019-0007.

B. Despite Intervening Legal Developments and Significant Opposition to the Proposed Reversal of Nondiscrimination Protections, HHS Published the 2020 Rule with Minimal Changes From the 2019 NPRM.

On June 19, 2020, HHS published the 2020 Rule, which made only "minor and primarily technical corrections" to the 2019 NPRM, notwithstanding the substantial number of public comments opposing the proposed rule. 85 Fed. Reg. at 37,161. The 2020 Rule was issued four days after the Supreme Court's June 15, 2020 decision in *Bostock*, in which the Supreme Court held that the prohibition on discrimination on the basis of sex under Title VII of the Civil Rights Act of 1964 necessarily encompassed discrimination based on transgender status and sexual orientation. 140 S. Ct. at 1737. Although HHS had previously acknowledged in the 2019 NPRM that the Supreme Court's anticipated decision in *Bostock* "will likely have ramifications" on Section 1557's sex discrimination prohibition and application to transgender people, 84 Fed. Reg. at 27,855, the 2020 Rule did not acknowledge or account in any way for the Court's decision in *Bostock*. To the contrary, the 2020 Rule cited the federal government's *briefs* in *Bostock*, 85 Fed. Reg. at 37,178 & n.74, which had argued for the narrow interpretation of sex discrimination that the Supreme Court ultimately rejected. *See Bostock*, 140 S. Ct. at 1738-39.

In addition, the 2020 Rule adopted all of the proposed amendments to HHS's Section 1557 regulations, Title IX regulations, and CMS regulations, with minimal changes. 85 Fed. Reg. at 37,160. Specifically, the 2020 Rule: (1) narrowly construes Section 1557 to exclude certain health insurers and all HHS health programs not administered under Title I of the ACA from the regulation's scope, *id.* at 37,162, 37,244-45 (§ 92.3); (2) removes the definition of "on the basis of sex" that enumerated gender identity, sex stereotyping, and pregnancy-related conditions as forms of prohibited sex discrimination, and the express prohibitions on discrimination against transgender people, *id.* at 37,161-62; (3) abandons the robust language

access requirements of the 2016 Rule by, among other things, eliminating requirements that covered entities notify LEP individuals of their rights, and reducing entities' obligations to ensure that LEP individuals are afforded appropriate language access services while seeking and obtaining health care, *id.* at 37,162, 37,245-46 (§ 92.101); and (4) adopts broad religious exemptions to permit religiously-affiliated providers, health systems, and insurers to deny care and coverage in a manner otherwise prohibited by Section 1557, *id.* at 37,245 (§ 92.6(b)).

C. Federal Courts Have Preliminarily Enjoined Parts of the 2020 Rule.

Two federal district courts have preliminarily enjoined HHS from enforcing aspects of the 2020 Rule. *See Walker*, 2020 WL 4749859, at *1, 10 (holding that the repeal of the definition of "on the basis of sex" was contrary to law and arbitrary and capricious, enjoining enforcement of that repeal);[7] *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, --- F.Supp.3d ----, 2020 WL 5232076, at *45 (D.D.C. Sept. 2, 2020) (holding the repeal of the definition of "on the basis of sex" "insofar as it includes 'discrimination on the basis of . . . sex stereotyping" and the incorporation of Title IX's religious exemption were arbitrary and capricious, and preliminarily enjoining enforcement of those provisions).[8]

STANDARD OF REVIEW

Under the APA, courts must "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or that is "in excess of statutory . . . authority." 5 U.S.C. §§ 706(2)(A), (C). The APA requires "plenary review of the Secretary's decision." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S.

[7] On September 8, 2020, the court directed the parties to submit supplemental briefing on whether the stay should be expanded to include other parts of the 2020 Rule. *See* Ex. 4 (*Walker*, Electronic Order (E.D.N.Y. Sept. 8, 2020)).
[8] In a third lawsuit, a court denied the State of Washington's preliminary injunction motion on standing grounds, without reaching the merits. *See Wash. v. U.S. Dep't of Health & Human Servs.*, No. C20-1105JLR, 2020 WL 5095467, at *1 (W.D. Wash. Aug. 28, 2020). Because Plaintiffs' standing here rests on different grounds and with more robust evidentiary support than was presented in that case, *see infra* at 13-26, the *Washington* decision has little bearing on the standing inquiry here.

402, 420 (1971). Summary judgment is proper where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322-323 (1986). APA claims are "amenable to summary disposition" because "the entire case on review is a question of law." *N.Y. v. U.S. Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 516 (S.D.N.Y. 2019), *appeal filed*, No. 20-41 (2d Cir. Jan. 3, 2020) (citations, quotation marks, and modifications omitted).

ARGUMENT

I. PLAINTIFFS HAVE STANDING TO CHALLENGE THE 2020 RULE.

To show standing, a "plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). "States are not normal litigants for the purposes of invoking federal jurisdiction" and are entitled to "special solicitude" when evaluating standing. *Mass. v. EPA*, 549 U.S. 497, 518, 520 (2007); *see also N.Y. v. Mnuchin*, 408 F. Supp. 3d 399, 408 (S.D.N.Y. 2019).

To satisfy the injury-in-fact requirement, a plaintiff must show either actual or imminent harm or a "concrete" risk of harm. *Spokeo*, 136 S. Ct. at 1548; *see also NRDC v. FDA*, 710 F.3d 71, 82 (2d Cir. 2013) (requiring a "credible threat" of harm). Allegations of a "future injury" qualify "if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (internal quotation marks omitted). The injury "need not be large," and "an identifiable trifle will suffice." *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002) (internal quotation marks omitted).

The 2016 Rule created a federal enforcement scheme for health care discrimination under Section 1557 that operated in parallel to various state enforcement schemes for state laws

prohibiting discrimination by health care providers and insurers. The practical result of this system was that HHS and the states shared responsibility for both the enforcement of laws prohibiting health care discrimination, and the education of patients and regulated parties about their rights and obligations under federal and state civil rights laws. With the 2020 Rule, HHS abdicates its enforcement role in significant respects, leaving responsibility for enforcing certain protections entirely to the States. The 2020 Rule significantly reduces the breadth and scope of longstanding Section 1557 protections, blunting an important tool in combatting discrimination within the States and creating confusion among providers, insurers, and the States' residents.

The "predictable effect[s]" of the 2020 Rule give the States standing. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2566 (2019); *cf. Whitman-Walker*, 2020 WL 5232076, at *12, 15 (holding that patients' apprehension of encountering discrimination sufficiently supported standing to challenge 2020 Rule's elimination of the 2016 Rule's definition of sex discrimination and incorporation of Title IX's religious exemption). Unless the 2020 Rule is vacated, the States will suffer four independent injuries traceable to the Rule and redressable by the requested relief: (1) the Rule will force the States to bear new administrative and regulatory costs; (2) the Rule will impose additional investigation and enforcement costs on the States; (3) the Rule will harm the States' *parens patriae* interests in the health and well-being of their residents; and (4) the States will bear the burden of higher health care costs arising from adverse health impacts attributable to the Rule.

A. Plaintiffs Have Incurred and Will Continue to Incur Regulatory Burdens and Administrative Costs Addressing the Rule's Policy Reversals.

"Monetary expenditures to mitigate and recover from harms that could have been prevented absent [agency action] are precisely the kind of 'pocketbook' injury that constitute an injury to a proprietary interest for standing purposes." *N.Y. v. Scalia*, No. 20-cv-1689, 2020 WL

5370871, at *10 (S.D.N.Y. Sept. 8, 2020) (quoting *N.Y. v. U.S. Dep't of Labor*, 363 F. Supp. 3d 109, 126 (D.D.C. 2019)); *see also N.Y. v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 59-60 & n.16 (2d Cir. Aug. 4, 2020). Plaintiffs may base standing on "reasonably incur[red] costs to . . . avoid" a substantial risk of harm. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409, 414 n.5 (2013). The Rule creates a divergence between HHS's Section 1557 regulations and state laws prohibiting health care discrimination. Many of the States have statutory, regulatory, or sub-regulatory protections against discrimination that provide similar protections as the 2016 Rule and HHS's broad interpretation and enforcement of Section 1557 after the ACA was enacted, *see infra* Section I.B., and now offer more robust protections than the 2020 Rule.[9]

Particularly considering the Rule's effective invitation to health providers and insurers to discriminate against transgender people and other vulnerable groups, *see* 85 Fed. Reg. at 37,225 (contemplating that some entities may reverse policies protecting transgender people because of the Rule), the States must ensure that providers and insurers in their jurisdictions understand their continuing nondiscrimination obligations under state law.[10] To that end, the States have incurred and will incur costs issuing guidance and directives confirming that their state agencies will—in contrast to HHS—(1) investigate discrimination in health care by a broad range of

[9] *See* Ex. 5 ¶¶ 6, 12, 15 (Lara Decl); Ex. 6 ¶ 5 (Kish Decl.) (CA); Ex. 7 ¶¶ 8, 11 (Bimestefer Decl.) (CO); Ex. 8 ¶¶ 9, 11-15, 21 (Conway Decl.); Ex. 9 ¶ 8, 11 (Hughes Decl.) (CT); Ex. 10 ¶¶ 6-7, 10 (Codes-Johnson Decl.); Ex. 11 ¶ 6 (Fullman Decl.) (DE); Ex. 12 ¶ 9 (Kofman Decl.) (DC); Ex. 13 ¶¶ 5-7, 10 (Planthold Decl.); Ex. 14 ¶¶ 6-10; 13 (Madden Decl.) (IL); Ex. 15 ¶ 5 (Sneirson Decl.); Ex. 16 ¶ 7 (Amaez Decl.) (ME); Ex. 17 ¶¶ 4, 6 (Gillard Decl.); Ex. 18 ¶ 6 (Eberle Decl.) (MD); Ex. 19 ¶ 5, 7 (Boyle Decl.); Ex. 20 ¶¶ 7-8, 10 (Beagan Decl.); Ex. 21 ¶¶ 5-8 (Thomas George Decl.) (MA); Ex. 22 ¶¶ 9-10 (Hailu Decl.); Ex. 23 ¶¶ 5, 8 (Vaynerman Decl.) (MN); Ex. 24 ¶¶ 6, 10 (Maylath Decl.) (NV); Ex. 25 ¶¶ 11-14 (Medina-Forrester Decl.); Ex. 26 ¶¶ 7-10 (Scahler-Haynes Decl.) (NJ); Ex. 27 ¶¶ 5, 7-9 (Comeaux Decl.); Ex. 28 ¶ 5 (Kunkel Decl.) (NM); Ex. 29 ¶ 9 (Powell Decl.); Ex. 30 ¶ 9 (Schell-Guy Decl.) (NY); Ex. 31 ¶¶ 11-12 (Wilson Decl.) (NC); Ex. 32 ¶ 5 (Novais Decl.) (RI); Ex. 33 ¶ 5 (Allen Decl.) (OR); Ex. 34 ¶ 9 (Strumolo Decl.) (VT); Ex. 35 ¶¶ 11, 13, 16 (Roem Decl.); Ex. 36 ¶ 8, 13 (Kimsey Decl.) (VA); Ex. 37 ¶¶ 4-7 (Houdek Decl.) (WI).

[10] *See, e.g.*, Ex. 5 ¶¶ 6, 10-12 (Lara Decl.) (discussing California's efforts to combat discrimination, including against transgender individuals and other vulnerable Californians, to avoid confusion regarding civil rights protections which results in patients forgoing or delaying access to medical care, and other public health harms).

entities, including private insurance companies providing employer-based plans; (2) investigate complaints alleging discrimination on the basis of gender identity, sexual orientation, and pregnancy status; and (3) continue to require language access and interpretive services.[11] For example, the California Department of Insurance ("CDI") has already incurred costs to issue a notice to all California health insurers clarifying that the Rule does not preempt state law and that health insurers must continue to comply with California's anti-discrimination laws.[12] Other states have similarly issued bulletins and directives to regulated entities detailing state law protections and obligations in light of the divergence from federal law.[13] Therefore, the "States have standing based on the [Rule's] direct imposition of an increased regulatory burden on them." *Scalia*, 2020 WL 5370871, at *10. This evidence alone establishes standing. *Id.*

In addition, the Rule engenders substantial confusion and fear of discrimination among health care consumers. Many individuals previously covered by the 2016 Rule's protections are already distressed by the Rule, as they do not know if they will be able to rely on state-level protections instead or are unaware of state law protections.[14] With respect to LEP consumers,

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[11] *See* Ex. 13 ¶¶ 10, 11 (Planthold Decl.); Ex. 14 ¶¶ 16, 17 (Madden Decl.); Ex. 37 ¶ 4 (Black Decl.) (IL); Ex. 16 ¶¶ 9, 10 (Amaez Decl.) (ME); Ex. 22 ¶ 13 (Hailu Decl.) (MN); Ex. 24 ¶¶ 9, 13 (Maylath Decl.) (NV); Ex. 28 ¶ 5 (Kunkel Decl.) (NM); Ex. 29 ¶¶ 12-15 (Powell Decl.) (NY); Ex. 33 ¶ 5 (Allen Decl.) (OR); Ex. 32 ¶ 6 (Novais Decl.) (RI); Ex. 36 ¶¶ 10-11 (Kimsey Decl.) (VA); Ex. 38 ¶¶ 9-12 (Houdek Decl.) (WI).

[12] Ex. 5 ¶ 20 & Ex. A (Lara Decl.) (CA); Ex. 39 ¶ 5 & Ex. A (Cooper Decl.) (CA).

[13] For example, the Illinois Departments of Human Rights ("IL DHR"), Insurance ("IL DOI"), and Healthcare and Family Services ("IL DHFS") issued a joint agency communication "to clarify the 2020 Final Rule's impact on residents of Illinois, to identify the protections from discrimination that exist in State law, and to remind the healthcare community of their ongoing obligations to deliver healthcare services in a non-discriminatory manner," including on bases no longer covered under the Final Rule. Ex. 13 ¶ 11 (Planthold Decl.) (IL); Ex. 14 ¶ 16 & Ex. A (Madden Decl.) (IL). Similarly, the Wisconsin Office of the Commissioner of Insurance ("WI OCI") issued a bulletin clarifying legal requirements regarding nondiscrimination in health insurance coverage for individuals who are transgender or gender dysphoric, which required at least 10 hours of staff time. *See* Ex. 38 ¶¶ 9-10 (Houdek Decl.); Ex. 40 (Wis. Off. of Comm'r of Ins., *Nondiscrimination Regarding Coverage for Insureds Who Are Transgender or Gender Dysphoric* (June 29, 2020)). *See also* Ex. 19 ¶ 11 (Boyle Decl.) (MA); Ex. 29 ¶ 14(Powell Decl.) (NY); Ex. 33 ¶ 5 (Allen Decl.) (OR).

[14] *See* Ex. 41 ¶¶41-42 (Hughto Decl.); *see also* Ex. 42 ¶¶ 5-7 (Vera Decl.) (Trans Lifeline); Ex. 43 ¶¶ 11-12 (Davis Decl.) (Trevor Project); Ex. 8 ¶ 24 (Conway Decl.) (CO); Ex. 29 ¶ 10 (Powell Decl.) (NY); Ex. 33 ¶ 11 (Allen Decl.) (OR); Ex. 43 ¶ 12 (Lewis Decl.) (Side by Side); Ex. 45 ¶ 9 (Jones Decl.) (WI).

HHS even anticipated this outcome, yet took no action to remedy it. *See* 85 Fed. Reg. at 37,234 (acknowledging that LEP individuals may not be made aware of their right to file complaints with OCR due to the Rule).

Accordingly, States will be required to incur additional costs hiring staff, training staff, and educating providers and the public to address confusion and residents' fear of discrimination caused by the Rule.[15] In California, for example, CDI expects that, because confusion triggered by the Rule will lead to additional calls to the Department, it will hire one or more compliance officers to field those inquiries.[16] Because of the elimination of the 2016 Rule's language assistance requirements, California's Department of Fair Employment and Housing ("CA DFEH") will need to mount a multi-lingual campaign to educate LEP Californians about their rights, with other states taking similar measures.[17] These costs are sufficient to establish standing. *See N.Y.*, 363 F. Supp. 3d at 127 (holding that states could challenge agency's final rule because they anticipated incurring expenses for consumer education initiatives); *see also Scalia*, 2020 WL 5370871, at *9-10 (same); *cf. Whitman-Walker*, 2020 WL 5232076.

B. The Rule Compels Plaintiffs to Incur Costs to Enforce State Civil Rights Protections for Violations That HHS Will Not Address Under Section 1557.

The 2020 Rule will also injure the States by causing them to incur additional costs through investigation and enforcement of state civil rights protections banning discrimination in health care. *See N.Y.*, 363 F. Supp. 3d at 125-27 (holding that states had standing because they

[15] *See, e.g.*, Ex. 5 ¶ 19 (Lara Decl.) (CA); Ex. 9 ¶ 13 (Hughes Decl.) (CT); Ex. 10 ¶ 11 (Codes-Johnson) (DE); Ex. 14 ¶ 19 (Madden Decl.) (IL); Ex. 12 ¶¶ 10-13 (Kofman Decl.) (DC); Ex. 18 ¶¶ 9-10 (Eberle Decl.) (MD); Ex. 21 ¶ 13 (Thomas George Decl.) (MA); Ex. 23 ¶ 8 (Vaynerman Decl.) (MN); Ex. 24 ¶ 14 (Maylath Decl.) (NV); Ex. 25 ¶ 15 (Medina-Forrester Decl.) (NJ); Ex. 26 ¶ 11 (Schaler-Hayes Decl.) (NJ); Ex. 31 ¶ 24 (Wilson Decl.) (NC); Ex. 46 ¶ 26 (Altman Decl.) (PA); Ex. 32 ¶¶ 7-8 (Novais Decl.) (RI); Ex. 36 ¶¶ 8-9 (Kimsey Decl.) (VA); Ex. 45 ¶¶ 10-11 (Jones Decl.) (WI).

[16] Ex. 5 ¶ 19 (Lara Decl.) (CA).

[17] *See* Ex. 6 ¶ 22 (Kish Decl.) (CA); *see also* Ex. 25 ¶ 17 (Medina-Forrester Decl.) (NJ); Ex. 33 ¶¶ 6, 9 (Allen Decl.) (OR); Ex. 36 ¶¶ 8-10 (Kimsey Decl.) (VA).

expected to use state resources to investigate consumer complaints and bring enforcement actions). "To maintain the same level of protection for their [residents], the States must increase the resources they devote to state-level analogues of the [ACA]." *Scalia*, 2020 WL 5370871, at *11. As the Rule limits the scope and breadth of OCR's federal enforcement against discrimination, individuals who previously would have sought assistance from OCR will seek assistance from state agencies.

As detailed above, the 2020 Rule curtails federal enforcement of nondiscrimination in health care and health insurance by, *inter alia*, (1) narrowing the range of covered entities to exclude certain private insurance plans; (2) creating a religious exemption for providers to invoke to deny care; (3) indicating that OCR will not investigate complaints of discrimination on the basis of sexual orientation, gender identity, and pregnancy status; and (4) rolling back notice and tagline requirements, which informed LEP individuals of their right to file complaints with OCR. Simultaneously, by suggesting that Section 1557's protections do not encompass discrimination on the basis of sexual orientation and gender identity, or that insurers need not cover transition-related care or cover other health services for transgender people in a nondiscriminatory manner, the Rule invites health care entities to rescind or reduce certain protections they previously understood to be required by the law.[18]

States will be forced to fill this enforcement gap, as they will now be the sole governmental authorities accepting and investigating claims of health care discrimination by all types of health care entities, including private insurance companies providing employer-based plans, as well as claims of discrimination against consumers on the basis of gender identity,

[18] *See* Ex. 41 ¶¶ 35-37 & n.36 (Hughto Decl.) (discussing expected increases in discrimination by healthcare providers and denied insurance claims for medically necessary procedures due to 2020 Rule and noting prevalence of religiously-affiliated providers who can deny care if in conflict with religious beliefs).

sexual orientation, and pregnancy status.[19] Failure to fill the gap left by OCR will lead to public health harms.[20] Therefore, the States have standing because the Rule "puts the States to a forced choice: They can permit their [residents] to suffer a decreased level of protection or increase the resources they devote to enforce" state law. *Scalia*, 2020 WL 5370871, at *12.

State agencies will be forced to shift enforcement priorities in order to manage their already-limited resources or incur costs by hiring additional investigators, counsel, data analysts, and other staff to properly investigate discrimination claims and enforce state laws. For example, CA DFEH does not have discretion to decline to process and investigate complaints within its jurisdiction, so any increase in complaints necessarily increases its workload.[21] CA DFEH anticipates that processing and resolving complaints that previously could have been filed with OCR could result in at least $1,346 to $2,308 of staff time per complaint, and that even a conservative estimate supports an increase of 24 complaints per year being filed by transgender individuals for discrimination in health care and insurance due to the Rule.[22] Even one additional complaint diverted to state agencies from OCR would cost Illinois roughly $4,695 and would cost Minnesota $2,200 to $3,000.[23] States will need to expend additional staff time and other resources, and incur additional costs, to address an increase of discrimination complaints that might otherwise have gone to OCR.[24]

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[19] *See id.* ¶ 55-57, 66.
[20] *See id.* ¶¶ 58-61, 66-67
[21] *See* Ex. 6 ¶ 7 (Kish Decl.) (CA); *see also* Ex. 36 ¶ 12 (Kimsey Decl.) (VA); Ex. 9 ¶ 15 (Hughes Decl.) (CT); Ex. 11 ¶ 8 (Fullman Decl.) (DE); Ex. 17 ¶ 9 (Gillard Decl.) (MD).
[22] *See* Ex. 6 ¶¶ 19-20 (Kish Decl.) (CA).
[23] *See* Ex. 14 ¶¶ 20-23 (Madden Decl.) (IL); Ex. 23 ¶¶ 6, 9 (Vaynerman Decl.) (MN).
[24] *See* Ex. 9 ¶¶ 13-15 (Hughes Decl.) (CT); Ex. 11 ¶¶ 19-20 (Fullman Decl.) (DE); Ex. 13 ¶ 14 (Planthold Decl.) (IL); Ex. 20 ¶¶ 12-13 (Beagan Decl.) (MA); Ex. 16 ¶ 11 (Amaez Decl.) (ME); Ex. 15 ¶¶ 7-11 (Sneirson Decl.) (ME); Ex. 24 ¶¶ 16-19 (Maylath Decl.) (NV); Ex. 26 ¶¶ 12-15 (Schaler-Hayes Decl.) (NJ); Ex. 25 ¶¶ 20-23 (Medina-Forrester Decl.) (NJ); Ex. 31 ¶ 38 (Wilson Decl.) (NC); Ex. 46 ¶¶ 27-28 (Altman Decl.) (PA); Ex. 47 ¶ 9 (Miller Decl.) (PA); Ex. 36 ¶¶ 11-16 (Kimsey Decl.) (VA); Ex. 38 ¶¶ 11-12 (Houdek Decl.) (WI).

The Rule is also forcing the States to incur costs to issue new regulations or legislation to fill the void left by HHS's decision to abdicate its enforcement obligations in the health care context. For example, New York's Department of Financial Services amended New York's insurance law and regulations to prohibit discrimination based on an insured's or prospective insured's actual or perceived sexual orientation, gender identity or expression, or transgender status and to prohibit policy exclusions for treatments related to gender transition, gender dysphoria, or gender incongruence.[25] In addition, New York's Office of Addiction Services and Supports initiated a rulemaking to amend regulations governing patient rights in its programs because of the Rule.[26] Other States have promulgated regulations and enacted new anti-discrimination laws applicable to health care to ensure that their residents will remain protected by state law regardless of HHS's efforts to narrow the protections afforded by Section 1557.[27] As noted below, however, these efforts cannot completely address the harms created by the 2020 Rule because the Rule excludes plans that are not subject to state antidiscrimination laws.[28]

C. Plaintiffs Have a Quasi-Sovereign Interest in Their Residents' Health and Well-Being.

To assert standing as *parens patriae*, a state must articulate "a quasi-sovereign interest in the health and well-being" of its residents. *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982). A state may invoke *parens patriae* interests in an action

[25] *See* Ex. 29 ¶ 9 (Powell Decl.) (NY).
[26] *See* Ex. 30 ¶ 11 (Schell-Guy Decl.) (NY).
[27] *See* Ex. 8 ¶¶ 11-16 (Conway Decl.) (CO); Ex. 18 ¶ 6 (Eberle Decl.) (MD); Ex. 17 ¶ 4 (Gillard Decl.) (MD); Ex. 35 ¶¶ 11, 16-19 (Roem Decl.) (VA).
[28] For example, Virginia passed House Bill 1429 to ensure that a patient cannot be denied coverage for health care services based on their gender identity that a cisgender person would be covered for under the same insurance plan. *See* Ex. 35 ¶ 16 (Roem Decl.); *see also* Va. Code Ann. § 38.2-3449.1. But the statute only affects people whose health insurance plans are regulated by the Commonwealth of Virginia, which do not include Medicare, plans purchased under the ACA, and self-insured plans. Ex. 35 ¶ 19 (Roem Decl.). Thus, Virginia cannot implement regulations to protect transition-related health care coverage for more than three-fourths of health insurance plans that are supposed to cover the health care needs of the Commonwealth's residents. *Id.*

against the federal government to enforce federal law. *Mass.*, 549 U.S. at 520 n.17. "[A]n injury to a state's quasi-sovereign interests, such as its interest in the 'health and well-being—both physical and economic—of its residents in general,' may sometimes be sufficient to support the state's standing to sue 'on behalf of [its] citizens.'" *N.Y.*, 408 F. Supp. 3d at 408 (quoting *Conn. v. Cahill*, 217 F.3d 93, 97 (2d Cir. 2000); *Conn. v. Physicians Health Servs. of Conn., Inc.*, 287 F.3d 110, 119 (2d Cir. 2002)).

Here, the States have strong *parens patriae* interests in the health and well-being of their residents. As detailed below, the record reflects that the 2020 Rule will likely lead to adverse health consequences for the States' residents. In addition, as described *infra* at 34-35, the Rule narrows the scope of Section 1557's applicability to exclude many programs and activities operated by HHS, *see* 85 Fed. Reg. at 37,162, 37,244-45, leaving Plaintiffs' residents with little to no recourse to redress complaints of discrimination by these federal programs and activities. The Rule also purports to exclude many insurance plans—including private insurance plans, FEHB plans, and Medicare Part B plans—which, in most cases, are not subject to state civil rights laws. *See supra* at 10.[29] The States' residents enrolled in such plans (e.g., FEHB plans or plans written in other states) will have no recourse with OCR or state enforcement agencies without HHS's exercise of its enforcement authority, yet they may still suffer the health and economic consequences of being denied coverage. 81 Fed. Reg. at 31,444; *id.* at 31,460-61.[30]

Courts in the Second Circuit have long permitted states to sue as *parens patriae* to enforce a federal law against a federal agency. *See Carey v. Klutznick*, 637 F.2d 834, 838 (2d Cir. 1980) (holding that "the State of New York has standing in its capacity as *parens patriae*" to

[29] *See also* Ex. 13 ¶¶ 14, 17, 18 (Planthold Decl.) (IL); Ex. 19 ¶ 12 (Boyle Decl.) (MA); Ex. 46 ¶¶ 11, 16-19 (Altman Decl.) (PA); Ex. 35 ¶ 19 (Roem Decl.) (VA).
[30] *See also* Ex. 41 ¶ 47 (Hughto Decl.).

sue Commerce Department based on harms that a Census undercount would impose on New York residents); *Vullo v. Office of the Comptroller of the Currency*, 378 F. Supp. 3d 271, 284 (S.D.N.Y. 2019) ("[S]tates possess standing to 'prevent[] an administrative agency from violating a federal statute' in order to 'vindicate the [c]ongressional will.'") (quoting *Abrams v. Heckler*, 582 F. Supp. 1155, 1159 (S.D.N.Y. 1984)).[31] Here, the States seek to do precisely that—vindicate the Congressional will in enacting the ACA against HHS's unlawful attempt to undermine the law. Thus, the States may invoke their *parens patriae* interests to sue Defendants.

D. Plaintiffs Will Also Face Increased Costs Associated with Uncompensated Health Care Resulting From the 2020 Rule.

The States also have standing based on the likely increase in uncompensated health care costs arising from the 2020 Rule. A state has standing to challenge federal action that increases health care costs paid by the state. *N.Y.*, 2020 WL 4457951, at *9-10; *N.Y. v. USDA*, No. 19-cv-2956, 2020 WL 1904009, at *5-9 (S.D.N.Y. Apr. 16, 2020). Here, the 2020 Rule will cause members of certain groups to delay and avoid treatment, resulting in more costly eventual treatment and worse health outcomes, and increasing the costs borne by State-funded health insurance programs and hospitals.

First, the 2020 Rule will harm the public health by deterring individuals from seeking timely medical treatment, resulting in delayed or denied care and related economic costs.[32] The Rule purports to remove and reduce federal regulatory protections for LGBTQ individuals, women and others seeking reproductive health care or with pregnancy-related conditions, LEP

[31] *See also N.Y. v. Sebelius*, No. 07-cv-1003, 2009 WL 1834599, at *12 (N.D.N.Y. June 22, 2009) ("[A] *parens patriae* claim seeking to compel federal compliance with federal law is permissible where a State's independent quasi-sovereign interest is implicated."); *City of N.Y. v. Heckler*, 578 F. Supp. 1109, 1123 (E.D.N.Y. 1984) (state had *parens patriae* standing), *aff'd*, 742 F.2d 729 (2d Cir. 1984); *N.Y. v. Schweiker*, 557 F. Supp. 354, 358, 362 (S.D.N.Y. 1983) (same); *N.Y. v. United States*, 65 F. Supp. 856, 872 (N.D.N.Y. 1946) (same), *aff'd*, 67 S. Ct. 1207 (1947).

[32] *See* Ex. 41 ¶¶ 40-42, 49-53, 66-67 (Hughto Decl.).

individuals, and other protected groups, and it does so during the worst public health crisis in a century. In so doing, the Rule will cause some individuals in these groups to delay or avoid seeking care, which itself causes worse health outcomes.[33] These harms are compounded by the ongoing COVID-19 pandemic.[34]

As individuals delay treatment due to fear of discrimination, health insurance programs funded partially by the States will face increased expenses. The public health harms wrought by the 2020 Rule will increase the States' direct health care expenses through higher costs for state-funded insurance and increased costs of care for uninsured patients. *See Cal. v. U.S. Dep't of Homeland Sec.*, No. 19-cv-04975, 2020 WL 4440668, at *5 (N.D. Cal. Aug. 3, 2020) (holding that state plaintiffs demonstrated standing in their challenge to DHS's public charge rule, which would deter individuals from seeking timely health care, based on increased costs to states from individuals' delayed treatment). Many of the States administer and oversee multiple federal- and state-funded health care programs, including, for example, Medicaid and the Children's Health Insurance Program; operate or provide substantial funding to public hospitals; and cover the cost of care when patients do not have insurance.[35] When plans covered by the 2016 Rule but not

[33] *See* Ex. 39 ¶¶ 7-10 (Cooper Decl.) (CA); Ex. 5 ¶ 6 (Lara Decl.) (CA); Ex. 48 ¶¶ 6-15 (Starr Decl.) (CA); Ex. 10 ¶ 23 (Codes-Johnson Decl.) (DE); Ex. 14 ¶ 26 (Madden Decl.) (IL); Ex. 51 ¶ 15 (Jegede Decl.) (MI); Ex. 25 ¶¶ 25-29 (Medina-Forrester Decl.) (NJ); Ex. 27 ¶ 15 (Comeaux Decl.) (NM); Ex. 28 ¶¶ 6-8 (Kunkel Decl.) (NM); Ex. 33 ¶ 11 (Allen Decl.) (OR); Ex. 49 ¶¶ 16-18 (Levine Decl.) (PA); Ex. 44 ¶ 10 (Lewis Decl.) (Side by Side); Ex. 45 ¶¶ 13-18, 20 Jones Decl. (WI); Ex. 41 ¶¶ 44-46 (Hughto Decl.) (stating that, as a result of the Rule, healthcare avoidance among transgender individuals will increase, resulting in poor physical and mental health outcomes, such as increased morbidity and mortality); *see also* 81 Fed. Reg. at 31,444 (conceding that individuals who have experienced health care discrimination often postpone or do not seek needed care, resulting in adverse health outcomes).

[34] *See* Ex. 48 ¶¶ 7, 10, 15 (Starr Decl.) (CA); Ex. 14 ¶ 26 (Madden Decl.) (IL); Ex. 24 ¶¶ 26, 31 (Maylath Decl.) (NV); Ex. 25 ¶¶ 33-34 (Medina-Forrester Decl.) (NJ); Ex. 27 ¶ 16 (Comeaux Decl.) (NM); Ex. 28 ¶¶ 9-10 (Kunkel Decl.) (NM); Ex. 33 ¶ 7 (Allen Decl.) (OR); Ex. 50 ¶¶ 12-13 (Dolan Decl.) (VT); Ex. 45 ¶ 19 (Jones Decl.) (WI); Ex. 43 ¶ 11 (Davis Decl.) (Trevor Project)..

[35] *See* Ex. 39 ¶ 1 (Cooper Decl.) (CA); Ex. 7 ¶¶ 14-15 (Bimestefer Decl.) (CO); Ex. 10 ¶ 23 (Codes-Johnson Decl.) (DE); Ex. 19 ¶¶ 1, 6, 12 (Boyle Decl.) (MA); Ex. 52 ¶ 14 (Macomber Decl.) (MI); Ex. 24 ¶ 27 (Maylath Decl.) (NV); Ex. 25 ¶ 19 (Medina-Forrester Decl.) (NJ); Ex. 36 ¶ 6 (Kimsey Decl.) (VA); Ex. 45 ¶ 1 Jones Decl. (WI).

subject to the 2020 Rule (and not subject to state antidiscrimination laws) deny gender affirming care, some individuals will turn to state-funded care.[36]

In the 2016 Rule, HHS specifically found that *expanded* anti-discrimination protections would lead to a *decrease* in uncompensated care payments. 81 Fed. Reg. at 31,461 (recognizing that anti-discrimination protections under the 2016 Rule will contribute to a decrease in payments by the federal government for uncompensated care costs); *see also id*. at 31,460 (citing CDI report finding nondiscrimination protections for transgender individuals could result in cost savings associated with lower suicide rates, overall improvements in mental health, and lower rates of substance abuse). It follows that *narrowing* nondiscrimination protections will lead to an *increase* in uncompensated care costs to the States. *See Whitman-Walker*, 2020 WL 5232076, at *14-15 (finding that the elimination of the definition of "on the basis of sex" and incorporation of Title IX's religious exemption have and will continue to increase fears of discrimination by LGBTQ individuals, and that restoring those provisions would mitigate those fears and attendant health costs); *see also supra* at 22-25.

HHS has effectively conceded that by removing anti-discrimination protections, the Rule will cause the States to bear increased health care costs. HHS acknowledges that "individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity [] would no longer receive those benefits after publication of this rule." 85 Fed. Reg. at 37,225. HHS recognizes that "greater public health costs, cost-shifting, and expenses . . . may result from entities changing their nondiscrimination policies and procedures after promulgation of this rule." *Id.* Additionally, HHS acknowledges that repealing the requirements for translated notices and taglines for LEP individuals "may impose costs, such as decreasing

[36] *See, e.g.*, Ex. 47 ¶ 8 (Miller Decl.) (PA).

access to, and utilization of, healthcare for non-English speakers by reducing their awareness of available translation services." *Id.* at 37,232. Some of these costs necessarily will be borne by the States. *See Cal.*, 2020 WL 4440668, at *5; *cf. Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 593 (2012) ("*NFIB*") (Ginsburg, J., concurring in part) ("Health-care providers do not absorb these bad debts. Instead, they raise their prices, passing along the cost of uncompensated care to those who do pay reliably: the government and private insurance companies.")

These costs are more than sufficient to establish standing. *See N.Y.*, 2020 WL 4457951, at *9-10; *Air All. Houston v. EPA*, 906 F.3d 1049, 1059-60 (D.C. Cir. 2018); *N.Y.*, 2020 WL 1904009, at *7-9 (standing based on an increase in state health care costs); *D.C. v. USDA*, 444 F. Supp. 3d 1, 37 (D.D.C. 2020) (finding standing where agency "has actually 'done much of the legwork in establishing'" harm) (quoting *Mass. v. U.S. Dep't of Health & Human Servs.*, 923 F.3d 209, 224-25 (1st Cir. 2019)).

E. Plaintiffs' Injuries Are Traceable to the Rule and Would Be Redressed by a Vacatur of the Rule.

The States' injuries are traceable to the 2020 Rule, and a favorable decision would redress these injuries. *See, e.g.*, *N.Y.*, 363 F. Supp. 3d at 127; *see also Whitman-Walker*, 2020 WL 5232076, at *12, 15. "[I]t is well-settled that for standing purposes, petitioners need not prove a cause-and-effect relationship with absolute certainty; substantial likelihood of the alleged causality meets the test." *NRDC v. NHTSA*, 894 F.3d 95, 104-05 (2d Cir. 2018) (delaying penalty increase for automakers that violate fuel standards would lead automakers to violate those standards more frequently, and thus cause more pollution that would injure the plaintiffs (internal quotation marks and alteration omitted)); *see also NRDC v. U.S. Dep't of the Interior*, 397 F. Supp. 3d 430, 440 (S.D.N.Y. 2019). "This is true even in cases where the injury hinges on the reactions of the third parties . . . to the agency's conduct." *Id.* (citation omitted).

Here, it is a "predictable effect of Government action on the decisions of third parties," *Dep't of Commerce*, 139 S. Ct. at 2566, that the 2020 Rule's shrinking of protections will likely cause insurers and providers to discriminate against LGBTQ individuals, persons seeking reproductive health care or with pregnancy-related conditions, LEP individuals, and others. *See, e.g.*, *NRDC*, 397 F. Supp. 3d at 440. It is also predictable that the divergence between federal and state standards will cause confusion and fear of discrimination, will shift enforcement costs to the States, and increase uncompensated care costs for the States. *See Whitman-Walker*, 2020 WL 5232076, at *12 (noting it is "far from conjectural" that "anxiety surrounding the possibility of discrimination and denial of treatment is substantially likely to provoke" patients' fear of discrimination at the hands of third parties and cause individuals to delay care.).[37] This easily meets the traceability standard.

II. THE 2020 RULE IS CONTRARY TO LAW.

The APA requires courts to "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A). "[T]he APA requires a court to determine whether a decision is 'in accordance with law' as it exists at the time of review." *N.Y.*, 414 F. Supp. at 535 (citing *Georgetown Univ. Hosp. v. Bowen*, 698 F. Supp. 290, 297 (D.D.C. 1987), *aff'd*, 862 F.2d 323 (D.C. Cir. 1988)). The Rule is contrary to law because, in contravention of Section 1557's text and controlling case law, it: (1) narrows the scope of health programs and activities subject to Section 1557 by excluding many private health insurers and many of HHS's own programs; (2) eliminates the definition of discrimination "on the basis of sex" and express protections for transgender people, based on HHS's erroneous view that federal sex discrimination laws do not protect transgender people, a position rejected by the Supreme Court

[37] *See also* Ex. 41 ¶¶ 49-53, 65 (Hughto Decl.).

in *Bostock*; and (3) removes express prohibitions on sexual orientation and gender identity discrimination under unrelated CMS regulations based on that same legal error.

A. The Rule Drastically Narrows the Scope of Section 1557's Application in Contravention of the ACA.

Section 1557 prohibits discrimination by "any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)." 42 U.S.C. § 18116(a). The Rule narrows the scope of its application by excluding from Section 1557's reach: (1) all insurance plans offered by private health insurers that receive federal funding, except for the specific plans that receive such funding, and (2) all HHS health programs and activities, except for those administered under Title I of the ACA. 85 Fed. Reg. at 37,244-45 (45 C.F.R. § 92.3). These limitations are contrary to Section 1557, in violation of the APA. 5 U.S.C. § 706(2)(A).

1. The Rule impermissibly redefines "health program or activity" to exclude certain health insurers and other entities not "principally engaged" in providing medical treatments directly to patients.

a. Section 1557's plain text unambiguously applies to all operations of health programs and activities receiving federal financial assistance, including health insurance companies.

The Rule purports to define the unambiguous statutory phrase "any health program or activity, *any part of which* is receiving Federal financial assistance," 42 U.S.C. § 18116(a) (emphasis added), as limited to "all of the operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance," 85 Fed. Reg. at 37,244 (§ 92.3(b)). Under the Rule, "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare." *Id.* at 36,244-45 (§ 92.3(c)).

HHS's construction of the statute excludes "an entity principally or otherwise engaged in providing health insurance" by replacing the statutory term "health" with the word "healthcare," and then asserting, without basis, that health insurers are not "principally engaged in the business of providing healthcare." *Id.* In doing so, HHS unlawfully rewrites the statute and adopts an interpretation at odds with Section 1557's text and the ACA's overarching objective of eliminating barriers to health insurance coverage in the United States. *See King*, 576 U.S. at 478; *NFIB*, 567 U.S. at 519; *N.Y.*, 414 F. Supp. 3d at 502.

In assessing whether an agency's interpretation of a statute is permissible, courts apply the two-step framework announced in *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984). *See King*, 576 U.S. at 485; *Hedges v. Obama*, 724 F.3d 170, 189 (2d Cir. 2013). "Under that framework, we ask whether the statute is ambiguous and, if so, whether the agency's interpretation is reasonable." *King*, 576 U.S. at 485 (2015). Where, as here, the agency's interpretation of a statute conflicts with the statute's unambiguous language, it is entitled to no deference and the "judicial inquiry is complete." *Hedges*, 724 F.3d at 189. "[W]hen deciding whether the language is plain, we must read the words in their context and with a view to their place in the overall statutory scheme." *King*, 576 U.S. at 486 (internal citations, quotation marks, and modifications omitted); *see also Hedges*, 724 F.3d at 189.

Section 1557, by its plain statutory terms, applies to "any health program or activity, any part of which is receiving Federal financial assistance[.]" 42 U.S.C. § 18116(a). Accordingly, Section 1557 applies to all aspects of a covered health program or activity, not just those aspects that receive federal assistance. A health insurer plainly qualifies as a health program. *See Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 948, 954-55 (9th Cir. 2020). By adopting the broad term "health," Congress intended for Section 1557 to apply broadly to all the

operations of all health providers, insurers, and other federally funded health programs. This expansive language is consistent with the ACA's central statutory objective of expanding access to health care by eliminating various barriers to health coverage—including discriminatory policies and practices of health insurers. *See King*, 576 U.S. at 478; *Schmitt*, 965 F.3d at 949, 955. Accordingly, federal courts have consistently interpreted Section 1557, by its plain text, to apply to health insurers. *See Schmitt*, 965 F.3d at 951 (holding that Section 1557 "prohibits discrimination . . . in the health care system—as relevant here, in health insurance contracts"); *Tovar v. Essentia Health*, 857 F.3d 771, 779 (8th Cir. 2017) (reversing dismissal of Section 1557 claims against insurer). No court has held otherwise.

When Section 1557's text is considered in the context of the ACA as a whole, there is no question that the provision was intended to apply to health insurers. Section 1557 is part of the ACA's "series of interlocking reforms designed to expand coverage in the individual health insurance market," *King*, 576 U.S. at 478, and in the "national market for health-care products and services," *NFIB*, 567 U.S. at 590. Reading "health insurance" out of "health program and activity" defies the plain text of Section 1557 and the ACA's broader purpose of eliminating barriers to health care, including discrimination in the insurance context.

b. Even if the term "health program or activity" were ambiguous, HHS's interpretation is not based on a permissible construction of the statute.

This Court need only proceed to the second step of the *Chevron* inquiry—whether the agency's interpretation is "based on a permissible construction of the statute"—if it finds that the statute is "silent or ambiguous with respect to the specific issue[.]" *Chevron*, 467 U.S. at 843; *see also Lawrence + Mem'l Hosp. v. Burwell*, 812 F.3d 257, 267-68 (2d Cir. 2015). As explained above, the statutory language is unambiguous. But even if this Court were to disagree, HHS's exclusion of health insurers from the scope of "health program and activity" is not based

on a permissible construction of the statute because it (1) is contrary to the statutory scheme of the ACA as a whole, and (2) relies on an erroneous application of the Civil Rights Restoration Act of 1987 ("CRRA"), Pub. L. 100–259, 102 Stat. 28 (Mar. 22, 1988), as its primary basis for carving out health insurers from Section 1557's reach. *See* 85 Fed. Reg. at 37,171. Incorporation of the CRRA is unnecessary because Section 1557, by its own terms, applies to all aspects of federally-funded health programs and activities that receive any federal funding. Even if CRRA did apply to Section 1557, it does not support Defendants' cramped interpretation of "health program or activity" to eliminate protections for individuals covered by private insurance plans offered by health insurers that receive federal funding. A decision based on a misreading of the applicable law violates the APA and is not entitled to deference. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1912-13 (2020); *Mass.*, 549 U.S. at 528.

First, the exclusion of health insurers is, for the reasons described in the previous section, at odds with the ACA's statutory scheme of comprehensively reforming the health insurance market to reduce barriers to health care. *See supra* at 4-5. Interpreting Section 1557 narrowly to exempt health insurers from ACA's nondiscrimination mandates is unreasonable. *Cf. Cook Cty. v. Wolf*, 962 F.3d 208, 228 (7th Cir. 2020).

Second, HHS's incorporation of the CRRA to interpret Section 1557's scope is not plainly authorized by the statute and is, in any event, unnecessary. HHS's stated rationale for incorporating the CRRA to narrow the scope of Section 1557—that "Section 1557 explicitly incorporates statutes amended by the CRRA," 85 Fed. Reg. at 37,171-72—goes too far. Although Section 1557 incorporates the protected classifications and enforcement mechanisms of the Civil Rights Statutes, it does not expressly incorporate other provisions of those statutes. 42 U.S.C.§ 18116(a); *see also Schmitt*, 965 F.3d at 953; *Doe*, 926 F.3d at 239. As the definition

and scope of "program or activity" are neither a "ground prohibited" by or "enforcement mechanism provided for and available" under the Civil Rights Statutes, 42 U.S.C. § 18116(a), they were not expressly incorporated into Section 1557.

Incorporation of the CRRA is unnecessary because, under its plain text, Section 1557 already applies to all parts of health programs or activities that receive federal funding, not just the specific aspects that receive that funding. Unlike Section 1557, which applies to "*any* health program or activity, *any part of which* is receiving Federal financial assistance," 42 U.S.C. § 18116(a) (emphases added), the Civil Rights Statutes contained no such language when they were originally enacted. Although federal agencies had originally interpreted the Civil Rights Statutes, as originally written, to apply broadly to all aspects of a covered entity's operations, *see Doe v. Salvation Army in U.S.*, 685 F.3d 564, 567, 571-72 (6th Cir. 2012), the Supreme Court held in 1984 that these laws applied only to the specific programs or activities of an institution that receive federal funding and not entity-wide. *See Grove City Coll. v. Bell*, 465 U.S. 555, 573-74 (1984); *Consol. Rail Corp. v. Darrone*, 465 U.S. 624, 636 (1984). Congress, rejecting the Supreme Court's interpretation, passed the CRRA to "restore the previously broad scope of coverage of [those] four statutes" to *all* of the operations of covered entities, "any part of which is extended Federal financial assistance[.]" Pub. L. No. 100-259 §§ 2, 3, 4(2), 5(3), 6; *see also Salvation Army*, 685 F.3d at 571-72 ("Congress passed the Civil Rights Restoration Act of 1987 to restore the previously broad scope of coverage of the four statutes that used the word 'program or activity[.]'"). By including the phrase "any part of which" in Section 1557, Congress intended for the statute to mirror the language in the CRRA, ensuring that Section 1557's scope would apply entity-wide as Congress originally intended for the Civil Rights Statutes.

But even assuming *arguendo* that Section 1557 does incorporate the CRRA, the CRRA simply does not support HHS's exclusion of private health insurers. HHS incorrectly claims that, "with respect to the health sector, [the CRRA] applied those prohibitions to all health programs or activities receiving Federal financial assistance, but not to all providers of health insurance." 85 Fed. Reg. at 31,171. But the Civil Rights Statutes are *not* limited in application to "health programs or activities." Nor do those statutes explicitly or implicitly exclude health insurance companies. With respect to *private* entities receiving federal funding, the CRRA required that the Civil Rights Statutes apply entity-wide if the entity "is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation[.]" Pub. L. No. 100-259 §§ 3, 4(2), 5(3), 6. Even if the CRRA applied to Section 1557, that statute neither defines "health care" nor suggests that being "principally engaged in the business of providing . . . health care" excludes health insurance companies. Indeed, HHS cites *no* authority for the proposition that the CRRA applied "to all health programs or activities receiving Federal financial assistance, but not to all providers of health insurance." 85 Fed. Reg. at 37,171. And of course, health insurance is a fundamental part of the American health care system since most people cannot obtain health treatments and services without it.

Moreover, HHS ignores the definitions of "health program" and "health care" in the ACA itself, which refers elsewhere to both "health programs" and "health care entities" as including insurers and insurance plans. *See, e.g.*, Section 1331, 42 U.S.C. § 18051 (permitting states flexibility to provide a "basic health program" by offering "1 or more standard health plans providing at least the essential health benefits described in section 1302(b) to eligible individuals

in lieu of offering such individuals coverage through an Exchange");[38] Section 1553, 42 U.S.C. § 18113 (defining "health care entity" to include "*a health maintenance organization*, *a health insurance plan*, or any other kind of health care facility, organization, or *plan*.") (emphasis added).[39] Congress did not limit Section 1557's application to medical providers, nor does the text of Section 1557 or the ACA as a whole support HHS's narrow reading of "health care" to exclude health insurers. To the extent the ACA defines "health care" at all, it includes insurance necessary to access and pay for medical services.[40] These various provisions show that Congress could have chosen the term "health care" instead of "health" for Section 1557, but did not. Congress' varying definitions of "health care" in different contexts makes HHS's reliance on the definition of the term from other laws in interpreting Section 1557 unreasonable and entitled to no deference. *See Dep't of Homeland Sec.*, 140 S. Ct. at 1912-13; *Mass.*, 549 U.S. at 528.

For these reasons, the Rule's exclusion of private health insurance companies from Section 1557's scope is based on an erroneous and impermissible interpretation of the statute, is entitled to no deference, and is contrary to law.

[38] Other provisions of federal health law also define "health care program" to refer *exclusively* to health insurance programs. *See, e.g.*, Anti-Kickback Statute, Social Security Act, 42 U.S.C. § 1320a–7b(f) (defining "Federal health care program" as "(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government").

[39] Although HHS attempts to narrow the definition of health program under Section 1557 to reduce nondiscrimination protections for individuals on private insurance plans, the Department took a contradictory position in its "Conscience Rule" that purported to exempt a range of entities from providing certain health services. *N.Y.*, 414 F. Supp. 3d at 525-26. There, the HHS rule at issue impermissibly expanded the definition of "health care entity" to include not just health providers and insurers, as defined in the underlying statutes, but also to third-party administrators and plan sponsors, which were not. *Id*.

[40] HHS's reliance on definitions of "health care" in other statutes and regulations does not support its contention, 85 Fed. Reg. at 31,172, that Section 1557 does not apply to health insurers. *See* 5 U.S.C. § 5371 (a miscellaneous provision of a federal statute pertaining to government employee pay rates that applies only to that section of the federal code); 45 C.F.R. § 160.103 (providing a non-exhaustive definition of "health care" that includes providers).

2. The Rule unlawfully excludes many HHS health programs and activities.

Section 1557 also applies to "any program or activity that is administered by an Executive Agency *or* any entity established under this title (or amendments)." 42 U.S.C. § 18116(a) (emphasis added). In other words, the statute applies (a) to all health programs and activities administered by federal agencies, including HHS,[41] and (b) to other entities established under Title I of the ACA, which include the state-based and federally-facilitated health insurance marketplaces (i.e., exchanges) and other entities not administered by the federal government. *See* 42 U.S.C. §§ 18031(b), 18051, 18061; *see also* 81 Fed. Reg. at 31,468 (former § 92.4).

While the 2016 Rule followed the statutory text and applied Section 1557 to all health programs and activities operated by HHS *and* to any entity established under Title I, 81 Fed. Reg. at 31,466-67 (former § 92.4), the 2020 Rule unlawfully narrows the scope of the statutory protections to "[a]ny program or activity administered by the Department [of Health and Human Services] *under Title I*" or "[a]ny program or activity administered by any entity established under such Title." 85 Fed. Reg. at 37,244-45 (§ 92.3) (emphasis added). Accordingly, the Rule, in contravention of the text and statutory purpose of Section 1557, purports to exclude from Section 1557's scope all health programs and activities administered by HHS *except* for those administered under Title I of the ACA.[42] *Id.* This change will newly exclude HHS health programs and activities administered by CMS, the Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), the Health Resources and Services Administration (HRSA),

[41] Although the phrase "any program or activity that is administered by an Executive Agency," out of context, does not contain the word health, it is evident from its placement in the full statute that Congress intended for it to refer to health programs and activities.

[42] Programs and activities "administered by the Department under Title I" are limited to "temporary high-risk pools, temporary reinsurance for early retirees, Department mechanisms for identifying affordable health insurance coverage options, the wellness program demonstration project, the provision of community health insurance options, and the establishment of risk corridors." 85 Fed. Reg. at 37,227 (internal statutory citations omitted).

and Substance Abuse and Mental Health Services Administration (SAMHSA), among others. *See* 81 Fed. Reg. at 31,446; *see also Whitman-Walker*, 2020 WL 5232076, at *5.

HHS's construction of the statute as excluding many of HHS's own health programs and activities is fatally flawed. Under the statute, Section 1557 applies to any health program or activity "administered by an Executive Agency *or* any entity established under this title (or amendments)." 42 U.S.C. § 18116(a) (emphasis added). The Rule, ignoring the disjunctive "or" in that plain statutory text, incorrectly construes the words "established under this title (or amendments)" as modifying the phrase "administered by an Executive Agency." But under the rule of the last antecedent, a limiting phrase must be read as "modifying only the term immediately preceding it, unless a contrary intention is apparent," since to do otherwise would render statutory text superfluous. *Hedges*, 724 F.3d at 192 n.134 (citing *Am. Int'l Grp., Inc. v. Bank of Am. Corp.*, 712 F.3d 775, 782 (2d Cir. 2013); *Allard K. Lowenstein Int'l Human Rights Project v. Dep't of Homeland Sec.*, 626 F.3d 678, 681 (2d Cir. 2010)). By ignoring this rule of statutory construction, HHS effectively reads the statute as applying to "any program or activity . . . established under this title (or amendments)," rendering superfluous the words "administered by an Executive Agency or any entity." HHS does not point to contrary Congressional intent to limit Section 1557 in this manner. Nor does excluding most of HHS's own health programs and activities from Section 1557's ambit make sense in the context of the ACA's statutory purpose of eliminating barriers to health coverage and care throughout the American health care system, of which HHS's newly-excluded health programs and activities are a significant part. The 2020 Rule's limitation is, therefore, contrary to Section 1557's statutory text.

B. The Removal of the Definition of "On the Basis of Sex" and Corresponding Protections for Transgender People Conflicts with Section 1557.

The Rule's elimination of the 2016 Rule's definition of "on the basis of sex," 81 Fed. Reg. at 31,467 (former 45 C.F.R. § 92.4) and removal of the earlier rule's express prohibitions on discrimination against transgender people, *id.* at 31,471-72 (former §§ 92.206, 92.207), is contrary to law because it conflicts with Section 1557's statutory prohibition on discrimination "on the basis of sex." The 2020 Rule's removal of the prior regulation's definition of discrimination "on the basis of sex" was based solely on HHS's misconception that Section 1557 does not extend to transgender people, 85 Fed. Reg. at 37,168, 37,177-80, 37,183-97, and its concomitant and misplaced desire "to restore[] the rule of law by confining regulation within the scope of the Department's legal authority," *id.* at 37,163. Because that position is contrary to the plain text of Section 1557 and Title IX, and is flatly irreconcilable with *Bostock*, the removal of the definition is contrary to law. *See Walker*, 2020 WL 4749859, at *8-9 (rejecting HHS's argument that the definition's removal is "inconsequential" since "the premise of the repeal was a disagreement with a concept of sex discrimination later embraced by the Supreme Court").

It is now settled law that "it is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex," because "transgender status [is] inextricably bound up with sex." *Bostock*, 140 S. Ct. at 1742. In *Bostock*, Justice Gorsuch applied a straightforward, textual reading of Title VII's prohibition of discrimination "because of . . . sex." *Id.* at 1741-42. *Bostock* makes clear that discrimination based on transgender status is *per se* sex discrimination, *id.* at 1742, and affirms the overwhelming weight of prior authority applying another seminal Supreme Court decision, *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989), to hold that discrimination against transgender people is a form of

prohibited sex stereotyping.[43] Accordingly, every federal appeals court to consider the question has held that discrimination against transgender students violates Title IX, and, by extension, that discrimination against transgender individuals in health settings violates Section 1557. *See Grimm v. Gloucester Cty. Sch. Bd.*, --- F.3d ----, 2020 WL 5034430, at *1, 21 (4th Cir. Aug. 26, 2020); *Adams v. Sch. Bd. of St. Johns Cty.*, 968 F.3d 1286, 1304-05 (11th Cir. 2020); *Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017), *cert. dismissed*, 138 S. Ct. 1260 (2018).[44]

Accordingly, federal district courts have found that Section 1557's statutory prohibition of discrimination on the basis of sex extends to discrimination against transgender people. *See, e.g., Flack v. Wis. Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1014-15 (W.D. Wis. 2019) (incorporating sex discrimination analysis from *Flack v. Wis. Dep't of Health Servs.*, 328 F. Supp. 3d 931, 946-51 (W.D. Wis. 2018)) (holding that Wisconsin Medicaid's categorical exclusion on gender-affirming health treatments violated Section 1557); *Boyden v. Conlin*, 341 F. Supp. 3d 979, 997, 1002-03 (W.D. Wis. 2018) (striking down similar categorical exclusion under state employee health plan); *Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 953 (D. Minn. 2018) (denying motion to dismiss Section 1557 claim based on denial of coverage for gender-affirming treatment under a categorical exclusion); *Prescott v. Rady Children's Hosp.-San Diego*, 265 F. Supp. 3d 1090, 1098-1100 (S.D. Cal. 2017) (denying motion to dismiss Section 1557 claims arising from hospital employees' intentional misgendering of transgender boy).

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[43] *See, e.g.*, *EEOC v. R.G. & G.R. Harris Funeral Homes, Inc.*, 884 F.3d 560, 574-75 (6th Cir. 2018) (holding discrimination against transgender employee based on sex stereotypes and transgender status violated Title VII), *aff'd sub nom.*, *Bostock*, 140 S. Ct. at 1742-43; *Glenn v. Brumby*, 663 F.3d 1312, 1321 (11th Cir. 2011) (Fourteenth Amendment and Title VII); *Barnes v. City of Cincinnati*, 401 F.3d 729, 737 (6th Cir. 2005), *cert. denied*, 546 U.S. 1003 (2005) (Title VII); *Smith v. City of Salem*, 378 F.3d 566, 574-75 (6th Cir. 2004) (same); *Schwenk v. Hartford*, 204 F.3d 1187, 1200-02 (9th Cir. 2000) (Gender Motivated Violence Act); *Rosa v. Park W. Bank & Tr. Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act).

[44] *Grimm* and *Adams*, both decided after *Bostock*, expressly held that the Supreme Court's reasoning under Title VII applies with equal force to Title IX. *Grimm*, 2020 WL 5034430, at *21; *Adams*, 968 F.3d at 1305.

The central reasoning of all of this authority—that discrimination on the basis of sex necessarily prohibits discrimination based on transgender status—was confirmed by the Supreme Court's dispositive decision in *Bostock*. 140 S. Ct. at 1741-42. Although *Bostock* involved Title VII, *see id*. at 1753, its reasoning applies with equal force to Title IX and, by extension, to Section 1557. *See Adams*, 968 F.3d at 1304-05. As the Eleventh Circuit noted in *Adams*, both Title VII and Title IX "employ a 'but-for causation standard,' which *Bostock* found critical to its expansive interpretation of sex discrimination." *Id.* at 1305 (citing *Bostock*, 140 S. Ct. at 1739). Indeed, courts often look to Title VII to construe similar language in Title IX. *See id.*; *Whitaker*, 858 F.3d at 1047; *Yusuf v. Vassar Coll.*, 35 F.3d 709, 714 (2d Cir. 1994).

The 2020 Rule wholly ignores the fact that *Bostock* held that federal sex discrimination laws protect transgender people from discrimination based both on transgender status, and that *Price Waterhouse* and its progeny prohibit discrimination against all individuals, including transgender persons, for nonconformity to sex stereotypes.[45] Thus, HHS's reliance on its preferred, yet erroneous, interpretation of Section 1557 is clearly incompatible with the present state of the law, *see Walker*, 2020 WL 4749859, at *9, and its removal of protections for transgender people is contrary to law. *Id.*

C. The Rule's Removal of Express Prohibitions on Sexual Orientation and Gender Identity Discrimination from Unrelated HHS Regulations Is Contrary to Law.

Based on its stated desire to "conform" unrelated CMS regulations, HHS used the 2020 Rule to strip express prohibitions on sexual orientation and gender identity discrimination in

[45] To the extent Defendants argue that the definition's removal is nonetheless justified by the decision in *Franciscan Alliance v. Azar*, 414 F. Supp. 3d 928, 945 (N.D. Tex. 2019), *modified by* Order Modifying Final Judgment (N.D. Tex. Nov. 21, 2019) [Ex. 2], *appeal filed*, No. 20-10093 (5th Cir. Jan. 24, 2020), they are wrong. The central premise of *Franciscan Alliance*—that the inclusion of "gender identity" in the 2016 Rule's definition of "on the basis of sex" was not permitted by Title IX, *id.* at 942—was inconsistent with the weight of case law then and has now been squarely abrogated by *Bostock*. This Court's review of Plaintiffs' APA claims must be decided on the state of the law as it exists *now*. *See N.Y.*, 414 F. Supp. 3d at 535 (emphasis added).

CMS-funded managed care programs. 85 Fed. Reg. at 37,243 (codified at 42 C.F.R. §§ 438.3, 438.206, 440.262, 460.98, and 460.112). This is contrary to law in three ways.

First, the Rule purports to align the CMS regulations with Section 1557 based on the same faulty premise—to "return to the plain meaning of 'on the basis of sex,'" 85 Fed. Reg. at 37,162—that motivated HHS's unlawful removal of protections against gender identity and sex stereotyping discrimination from the Section 1557 regulations. *See supra* at 36-38.

Second, the eliminated protections against sexual orientation and gender identity discrimination were not added to the CMS regulations pursuant to Section 1557, nor were they adopted to comply with Section 1557. Rather, those protections were added as part of an unrelated set of CMS regulations promulgated in 2016 pursuant to HHS's authority under Section 1902 of the Social Security Act to provide methods of administration "necessary for the proper and efficient operation" of CMS programs. 42 U.S.C. § 1396A(a)(4); *see* 81 Fed. Reg. 27,498, 27,538 (May 8, 2016). HHS added those protections "to promote access and delivery of services without discrimination . . . to assure that care and services are provided in a manner consistent with the best interest of beneficiaries under section 1902(a)(19) of the Act," "to ensure access and provision of services in a culturally competent manner," and to ensure "the proper operation" of state plans. 81 Fed. Reg. at 27,538. In sum, the LGBTQ protections in these regulations were warranted regardless of the Supreme Court's decision in *Bostock*, and there would have been no cause for HHS to revisit them even if the Court had ruled differently.

Third, to the extent these amendments now authorize managed care programs regulated by those CMS regulations to discriminate based on sexual orientation or gender identity, they violate HHS's own obligation under Section 1557 to administer its health programs and activities in a nondiscriminatory manner. 42 U.S.C. § 18116(a).

III. THE RULE'S INCORPORATION OF TITLE IX'S BROAD RELIGIOUS EXEMPTION AND "ABORTION NEUTRALITY" PROVISION EXCEEDS HHS'S STATUTORY AUTHORITY.

Because neither Section 1557 nor any other provision of the ACA authorizes the Rule's incorporation of Title IX's broad religious exemption (20 U.S.C. §§ 1681(a)(3)) and "abortion neutrality" provision (20 U.S.C. § 1688), 85 Fed. Reg. at 37,245 (§ 92.6), those provisions were incorporated in excess of HHS's statutory authority, in violation of the APA, and must be set aside. 5 U.S.C. § 706(2)(C). An agency's authority to promulgate regulations "is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.,* 488 U.S. 204, 208 (1988). "[T]he question . . . is always whether the agency has gone beyond what Congress has permitted it to do[.]" *City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013).

Section 1557 contains no religious exemption, nor does it provide HHS authority to invent one by fiat. *See Andrus v. Glover Const. Co.*, 446 U.S. 608, 616-17 (1980) ("Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent."). To the contrary, Section 1557 makes clear that its nondiscrimination prohibitions apply broadly to all covered entities, "except as otherwise provided for in [Title I of the ACA]." 42 U.S.C. § 18116(a). Like Section 1557, Title I has no religious exemption or abortion exception.[46] However, the 2020 Rule ignores the statutory text by incorporating Title IX's religious exemption and "abortion neutrality" provision. 85 Fed. Reg. at 37,245 (§ 92.6). Under the Rule, "[n]othing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under . . . Title IX," and "[i]nsofar as the application of any requirement of this part would violate, depart from, or contradict definitions,

[46] As the court in *Whitman-Walker* noted, however, religiously-affiliated providers retain protections under other laws, such as the Religious Freedom Restoration Act, without the incorporation of Title IX's broad religious exemption. 2020 WL 5232076, at *29.

exemptions, affirmative rights, or protections cited in paragraph (a) of this section [including Title IX] . . . , such application shall not be imposed or required." *Id.* But, as explained above, Section 1557 incorporates *only* the protected classification and enforcement mechanisms from Title IX, not its exemptions. *See supra* at 4-5; *cf. Schmitt*, 965 F.3d at 953.

Since HHS lacks the authority to incorporate these sweeping exemptions into Section 1557, *see Bowen*, 488 U.S. at 208, the Rule's incorporation of these Title IX provisions to limit individuals' rights to obtain nondiscriminatory health care exceeds HHS's statutory authority, in violation of 5 U.S.C. § 706(2)(C).

IV. THE 2020 RULE IS ARBITRARY AND CAPRICIOUS.

Agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [made a decision that] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Courts must "consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *State Farm*, 463 U.S. at 43. While "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change," an agency must "'show that there are good reasons for the new policy,'" and "must also be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). Where an agency failed to provide a "reasoned explanation" for its departure from prior policy, the agency action is arbitrary and capricious. *Id*. (quoting *Fox*, 556 U.S. at 516).

The Rule is arbitrary and capricious because: (a) the rescission of the definition of "on the basis of sex" and express protections for transgender people is harmful and has no valid legal or factual basis; (b) the elimination of protections for limited English proficient persons frustrates Section 1557's purpose, is contrary to the weight of the evidence, and does not consider the harm to LEP individuals unable to access care; and (c) HHS failed to consider the harms resulting from the likely denial of care to individuals because of the incorporation of Title IX's religious exemption and "abortion neutrality" provision.

A. The Rule's Rescission of Sex Discrimination Protections for Transgender, Gender Nonconforming, and Pregnant Individuals Is Arbitrary and Capricious.

The Rule's elimination of express protections for transgender, gender nonconforming, and pregnant individuals is arbitrary and capricious because: (1) HHS's explanation for these changes is inconsistent with *Bostock* and other case law; (2) HHS failed to consider other important aspects of the problem, including harms to individuals and the public resulting from health care that is delayed or denied because of unlawful discrimination based on sex; and (3) the elimination of protections for transgender and gender nonconforming people is contrary to the agency's own factual findings demonstrating the necessity of such protections.

1. HHS's elimination of the definition of "on the basis of sex" and express prohibitions of discrimination against transgender individuals has no valid legal basis.

a. The Rule's removal of the express prohibition on gender identity discrimination failed to take Bostock *into account.*

The Rule is not only contrary to *Bostock*'s holding, *see supra* at 36-38, but it is also arbitrary and capricious because HHS failed to consider *Bostock*'s application to Section 1557. *See Whitman-Walker*, 2020 WL5232076, at *22; *Walker*, 2020 WL 4749859, at *9. Instead, HHS rushed to publish the Rule mere days after the Supreme Court's ruling in *Bostock*, even

though the *Bostock* decision struck at the heart of HHS's purported legal justifications for the Rule. *See Whitman-Walker*, 2020 WL 5232076, at *5, *25; *Walker*, 2020 WL 4749859, at *9. As the court held in *Walker*, "[w]hether or not it is dispositive of [the question of whether discrimination based on gender identity and sex stereotyping are forms of actionable sex discrimination] with respect to Title IX and § 1557, *Bostock* is at least 'an important aspect of the problem,'" that HHS failed to consider, rendering the repeal of the definition arbitrary and capricious. 2020 WL 4749859, at *9 (quoting *State Farm*, 463 U.S. at 43).

In the 2019 NPRM, HHS acknowledged that the Supreme Court's recent grant of certiorari in *Bostock* and two companion cases, and the anticipated rulings in those cases, would "likely have ramifications for the definition of 'sex' under Title IX" and Section 1557 "[b]ecause Title IX adopts the substantive and legal standards of Title VII." 84 Fed. Reg. 27,855. Nevertheless, HHS declined to wait for guidance from the Supreme Court before stripping protections for transgender people from its Section 1557 regulations based on the now rejected premise that federal sex discrimination laws protect against discrimination based only on the so-called "plain meaning of 'sex' as biologically binary." 85 Fed. Reg. at 37,190. That "plain meaning" had already been rejected by federal courts in numerous cases, *see supra* at 37, and *Bostock* confirmed before the Rule was published that HHS's narrow interpretation of Section 1557 and other federal sex discrimination laws was simply wrong.

Yet, when *Bostock* ultimately contradicted their favored position, Defendants published the Rule anyway, without acknowledging the decision or otherwise attempting to explain how the purported legal justifications for the Rule survived *Bostock*. Instead, HHS insisted in the Rule that it "is permitted to issue regulations on the basis of the statutory text and its best understanding of the law and need not delay a rule based on speculation as to what the Supreme

Court might say about a case dealing with related issues." 85 Fed. Reg. at 37,168. But even when there was no room for "speculation as to what the Supreme Court might say," *id*., HHS chose to publish the Rule as if such doubt remained.

Remarkably, HHS did not even revise the language *anticipating* the ramifications of *Bostock* on the agency's interpretation of Section 1557—despite the fact that the decision had already issued by the time of the Rule's publication. 85 Fed. Reg. at 37,168 ("The Department continues to expect that a holding from the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the basis of sex' under Title IX."). And the 2020 Rule continued to rely on the government's arguments briefed in *Bostock* and its underlying cases, even though the Supreme Court had squarely rejected those arguments. *See* 85 Fed. Reg. at 37,178, 37,184, 37,194.

To the extent that HHS argues that it was compelled to rescind the definition of "on the basis of sex" by the *Franciscan Alliance* decision, they are wrong. *See Whitman-Walker*, 2020 WL 5232076, at *25-26. Simply put, the district court's decision in *Franciscan Alliance* was based on the same erroneous interpretation of Title IX that HHS offers up to justify the rescission of transgender protections in the 2020 Rule: that Title IX does not protect transgender people. Like HHS's flawed reasoning here, the *Franciscan Alliance* court's interpretation of Title IX does not survive *Bostock*. *See Adams*, 968 F.3d at 1305; *Grimm*, 2020 WL 5034430, at *1, 21. In any event, *Franciscan Alliance* did not compel HHS to remove the full definition of "on the basis of sex," nor did it bar HHS from promulgating a regulation consistent with the correct interpretation of the law. *See Whitman-Walker*, 2020 WL 5232076, at *25-26.

HHS's failure to address or even acknowledge *Bostock*, despite HHS's own admission that the Court's ruling in that case would impact the interpretation of Title IX and Section 1557,

skipped an "obvious deliberative step" that falls short of the reasoned analysis required under the APA. *See id.* at *25. Accordingly, the rescission of the definition was arbitrary and capricious.

b. The Rule's elimination of the requirements that covered entities treat transgender individuals consistent with their gender identity was based on HHS's incorrect interpretation of discrimination "on the basis of sex."

The 2020 Rule's elimination of two essential protections for transgender individuals—that covered entities treat transgender people "consistent with their gender identity," 81 Fed. Reg. at 31,471 (former § 92.206), and not deny or limit coverage for services "ordinarily or exclusively available to individuals of one sex" to transgender people who need them, *id.* at 31,171-72 (former § 92.207(b)(3)-(5))—is arbitrary and capricious because it was based on HHS's erroneous view that discrimination "on the basis of sex" does not include discrimination against transgender people. *See* 85 Fed. Reg. at 37,177-92. Since this justification is legally incorrect, *see supra* at 36-38, it cannot suffice to justify the removal of these protections. *See Dep't of Homeland Sec.*, 140 S. Ct. at 1912-13; *Mass.*, 549 U.S. at 528. Because HHS offers no other rationale for deleting the former §§ 92.206 and 92.207(b)(3), the removal of those provisions was also arbitrary and capricious.

c. The Rule's removal of express prohibition of discrimination on the bases of sex stereotyping and pregnancy disregarded settled case law.

Even beyond *Bostock*, HHS failed to grapple meaningfully with the overwhelming weight of prior case law holding that discrimination against transgender and gender nonconforming people is a form of unlawful sex stereotyping prohibited by federal sex discrimination laws. *See Price Waterhouse*, 490 U.S. at 251 (Title VII); *Whitaker*, 858 F.3d at 1047-50 (Title IX); *Wolfe v. Fayetteville Sch. Dist.*, 648 F.3d 860, 867 (8th Cir. 2011) (Title IX). Instead, HHS simply dismissed these cases as espousing "novel legal theory advanced by these courts [that] represents a serious misreading of *Price Waterhouse* and of Title IX." 85 Fed. Reg.

at 37,184. Likewise, the Rule failed to consider controlling case law holding that federal sex discrimination laws prohibit discrimination based on pregnancy. *See UAW v. Johnson Controls, Inc.*, 499 U.S. 187, 198-99 (1991) (Title VII); *see also Conley v. Nw. Fla. State Coll.*, 145 F. Supp. 3d 1073, 1078 (N.D. Fla. 2015) (Title IX).

HHS's decision to disregard multiple circuit court cases finding protections for transgender people, to rely instead on a small handful of pre-*Bostock* district court cases and legal briefs supporting its preferred interpretation, and to fail to consider controlling case law on pregnancy discrimination, makes HHS's wholesale removal of the definition of "on the basis of sex" arbitrary and capricious.

2. The Rule's removal of express prohibitions on discrimination against transgender people is arbitrary and capricious.

The Rule's elimination of the express prohibition on categorical coverage exclusions on gender-affirming health care, 81 Fed. Reg. at 31,471-72 (former § 92.207(3)-(4)), is arbitrary and capricious because HHS: (a) failed to consider substantial evidence in the administrative record that gender-affirming health care is generally accepted in the medical community as safe, effective, and medically necessary when clinically indicated, and (b) reversed existing policy in disregard of the evidence before the agency that express protections are necessary to prevent harm to transgender individuals needing gender-affirming care to treat gender dysphoria.

HHS failed to consider or give any weight to the prevailing medical consensus that gender-affirming surgical and medical treatments for gender dysphoria, including those recognized by the World Professional Association of Transgender Health's *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* (7th Version 2012) (WPATH Standards of Care), are safe, effective, and, when clinically indicated, medically necessary. *See Grimm*, 2020 WL 5034430, at *3; *Edmo v. Corizon, Inc.*, 935 F.3d 757, 770 (9th

Cir. 2019); *Flack*, 395 F. Supp. 3d at 1018 ("any attempt by defendants or their experts to contend that gender-confirming care—including surgery—is inappropriate, unsafe, and ineffective is unreasonable, in the face of the existing medical consensus").

Ignoring the medical consensus and the weight of medical and scientific literature supporting that consensus, HHS simply asserted, without support, that the 2016 Rule's prohibition on categorical coverage exclusions "inappropriately interfered with the ethical and medical judgment of health professionals." 85 Fed. Reg. at 37,187. HHS cited only CMS's 2016 decision not to issue a national coverage determination for gender-affirming surgeries for Medicare beneficiaries,[47] a 2018 Department of Defense report, and irrelevant studies on childhood gender dysphoria. *See* 85 Fed. Reg. at 37,187.[48]

None of these sources refute the fact that gender-affirming medical care is generally accepted in the medical community as a treatment for gender dysphoria, a serious but treatable medical condition associated with the incongruence between one's gender identity and sex assigned at birth. *See Edmo*, 935 F.3d at 768 (citing WPATH Standards of Care); Am. Psychiatric Ass'n, Diagnostic & Statistical Manual of Mental Disorders ("DSM-5")); *Flack*, 395 F. Supp. 3d at 1018. While not all transgender people need medical treatments as part of a transition, it is medically necessary and often life-saving for many. *See Edmo*, 935 F.3d at 769 (discussing agreement of most courts and major medical and mental health organizations' agreement that the WPATH Standards of Care, which provide clinical guidelines for gender-

[47] This decision permitted gender-affirming treatments to be covered based on individual medical necessity, consistent with existing CMS policy, *see* U.S. Dep't of Health & Human Servs., No. A-13-87, Decision No. 2576 (Dep't Appeals Bd. May 30, 2014), and does not endorse categorical coverage exclusions as HHS suggests here.
[48] In *Whitman-Walker*, the court ruled, at the preliminary injunction stage, that HHS's consideration of these sources was reasonable. 2020 WL 5232076, at *31. But against the full record, for the reasons explained here, HHS's conclusion that there is no medical consensus is unsupported by the weight of the evidence before the agency. Moreover, the court in *Whitman-Walker* did not address HHS's failure to consider the harms of categorical exclusions, which independently makes the rescission of that prohibition arbitrary and capricious.

affirming hormone and surgical treatments, represent the medical consensus). HHS did not give any consideration or weight to that consensus, which was well-documented in the record.[49] Although the Rule recognizes that gender-affirming treatments may be necessary on a case-by-case basis, *id.* at 37,188, it does not explain how allowing insurers to maintain categorical exclusions for services deemed medically necessary to treat gender dysphoria, while covering identical services for other needs, can be justified. *See, e.g.*, *Flack*, 328 F. Supp. 3d at 950 (where an insurer "covers medically necessary treatment for other health conditions, yet . . . expressly singles out and bars a medically necessary treatment solely for transgender people suffering from gender dysphoria," it discriminates based on transgender status).

In the face of this evidence, HHS's conclusion that "there is no medical consensus to support one or another treatment for gender dysphoria," 85 Fed. Reg. at 37,188, is unsupportable. The relevant question, which HHS did not consider, is whether authorizing insurers to deny gender-affirming care, irrespective of medical necessity, denies health care to transgender people and results in harms to those individuals and the public health. The record makes clear that categorical coverage exclusions are discriminatory and harmful. HHS's failure to consider those harms and to rescind the prohibition on categorical exclusions despite the substantial evidence in the record of the harms of such exclusions, is arbitrary and capricious. *See Zzyym v. U.S. Dep't of State*, 958 F.3d 1014, 1023-25, 1027-31 (10th Cir. 2020); *Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 841 (D.C. Cir. 2006); *N.Y.*, 414 F. Supp. 3d at 540-41.

[49] *See, e.g.*, Ex. 53, at 5-6 (Nat'l All. of State & Territorial AIDS Dirs. cmt.); Ex. 54, at 2 (Nat'l Ass'n of Pediatric Nurse Practitioners cmt.); Ex. 55, at 7-8 & nn.13-18 (Jim Collins Found., Inc. cmt.); Ex. 56, at 2 (Yale New Haven Pediatric Gender Clinic cmt.); Ex. 57, at 1 (Mount Sinai Health Sys. cmt.); Ex. 58, at 4 & nn.31-32 (Am. Coll. of Obstetricians & Gynecologists cmt.); Ex. 59, at 5 & nn.19-20 (Nat'l Latina Inst. for Reprod. Health cmt.); Ex. 60, at 55-56 (Nat'l Health Law Program cmt.); Ex. 61, at 2-3 (Endocrine Soc'y cmt.).

3. HHS unlawfully eliminated nondiscrimination protections for transgender individuals without making any factual findings supporting those changes.

The 2016 Rule, which codified HHS's existing enforcement policy with respect to discrimination against transgender people, was based on factual findings of the widespread discrimination experienced by members of this population and the necessity of nondiscrimination protections to remove the resulting barriers to health care, gained in response to the 2013 RFI and 2015 NPRM. 80 Fed. Reg. at 54,172.

The reversal of HHS's policy is arbitrary and capricious because HHS did not make any factual findings contradicting its earlier justifications for the 2016 Rule, nor did it rebut its earlier findings demonstrating the need for that rule's protections. *See N.Y.*, 414 F. Supp. 3d at 547-49 (citing *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1284-85 (D.C. Cir. 2019)); *Scalia*, 2020 WL 5370871, at *31 ("An unexplained inconsistency in agency policy is a reason for holding that an interpretation is an arbitrary and capricious change from agency practice." (internal quotation marks omitted)). In the 2016 Rule, HHS stressed the importance of the rule in achieving the ACA's goal of expanding access to health care for all individuals, and further noted that discrimination in federal health programs contributes to poor coverage and inadequate health outcomes, exacerbates existing health disparities in underserved communities, and leads to ineffective distribution of health care resources. 81 Fed. Reg. at 31,444. HHS specifically found that anti-discrimination protections for transgender individuals, like those in the 2016 Rule, improve overall health and well-being, resulting in potential cost savings associated with properly treated gender dysphoria, including overall mental health improvement, lower rates of substance abuse, and reduced suicidality. 81 Fed. Reg. at 31,457, n. 353.

But now, based on essentially the same record—augmented extensively by comments *in opposition* to the 2019 NPRM—HHS discards these findings, summarily claiming it lacks data to

evaluate how the Rule will impact the LGBTQ community. 85 Fed. Reg. at 37,225 (dismissing comments the Rule will result in negative health consequences, increased costs for treatment of such conditions, cost shifting to transgender individuals, and increased burdens on the public health system due to the changes). HHS failed to explain its rejection of its earlier factual findings detailing the importance of anti-discrimination provisions in achieving the ACA's goal of expanding access to health care for all individuals. 81 Fed. Reg. at 31,444. Because HHS "must 'provide a more detailed justification than what would suffice for a new policy created on a blank slate,' and 'cannot simply disregard contrary or inconvenient factual determinations that it made in the past,'" *N.Y.*, 414 F. Supp. 3d at 550 (quoting *Fox*, 556 U.S. at 515; *id.* at 537 (Kennedy, J., concurring), its failure to do so here was arbitrary and capricious. *See Scalia*, 2020 WL 5370871, at *31 (holding that final rule was arbitrary and capricious where agency did not adequately explain why it departed from its prior interpretations).

4. HHS failed to consider important aspects of the problem, including individual and public health harms resulting from care that is delayed or denied because of unlawful sex discrimination.

HHS failed to consider or weigh the harms to individuals' health and well-being, and the associated public health costs to state and local governments, from its rescission of the 2016 Rule's definition of "on the basis of sex" and express protections for transgender people. "[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions," *i.e.*, the costs and benefits. *Mich. v. EPA*, 576 U.S. 73, 753 (2015). Listing a regulation's benefits without also considering its costs is insufficient. *See id.* Because HHS failed to quantify or meaningfully consider harms to affected groups and the public health despite evidence in the record and HHS's prior findings, the Rule is arbitrary and

capricious. *See Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017); *Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1072 (9th Cir. 2002).

a. HHS failed to consider the harms to LGBTQ people resulting from discrimination condoned by the Rule.

In the 2020 Rule, HHS admits that it expects many covered entities to remove protections for transgender and gender nonconforming people they had previously adopted in response to the Rule's removal of protections for those groups. HHS acknowledges that many covered entities "conform[ed] their policies and operations to reflect gender identity as a protected category" in response to the 2016 Rule's express protections for transgender people, 85 Fed. Reg. at 37,225, and now predicts that 50 percent of covered entities will revert their policies "to reflect this final rule's clarification of the application of Section 1557" and cease accepting and handling internal grievances based on gender identity and sex stereotyping, *id.* at 37,236-37.

This concession validates the concern expressed by multiple commenters that the Rule will make it more likely that LGBTQ patients will be discriminated against and deterred from obtaining care. *See* 85 Fed. Reg. at 37,191 ("Many commenters asserted that the proposed rule removes legal protections for transgender individuals and would allow or encourage providers to deny basic healthcare to individuals who identify as transgender.").[50] Data in the record documents the harm that discrimination in health care imposes on the LGBTQ community, especially transgender individuals, who already disproportionately experience discrimination and obstacles when seeking health care. 80 Fed. Reg. at 54,189-90 (discussing discriminatory

[50] HHS received many comments opposing the reversal of LGBTQ protections, including from medical groups, civil rights organizations, health advocates, and individuals. *See e.g.*, Ex. 62, at 4-5 (Am. Med. Ass'n cmt.); Ex. 63, at 2-3 (Am. Acad. of Pediatrics & Soc'y for Adolescent Health & Med. cmt.); Ex. 64, at 2 (Am. Hosp. Ass'n cmt.); Ex. 65, at 1-2 (Children's Hosp. Ass'n cmt.); Ex. 66, at 5-8 (Nat'l Ctr. for Lesbian Rights cmt.); Ex. 67, at 2-3 (Physicians for Reprod. Health cmt.); Ex. 68, at 2-3, 10 (Ctr. for Reprod. Rights cmt.); Ex. 69, at 2-3 (Advocates for Youth cmt.); Ex. 70, at 6-7 & n.18 (Chronic Illness & Disability P'ship cmt.); Ex. 71, at 6-7 (Lambda Legal cmt.); Ex. 72, at 2-3 (ACLU of Mich. cmt.); Ex. 73 (Uhrynowski cmt.); Ex. 74 (Williamson cmt.).

exclusions in health insurance coverage); *id*. at 54,208 (2010 survey wherein 26.7% of transgender respondents reported that they were outright refused needed health care); 81 Fed. Reg. at 31,429; *id*. at 31,460 (same). HHS previously recognized these harms and acknowledged that individuals who have experienced discrimination in health care often postpone or do not seek needed health care, leading to adverse health outcomes and related health and economic consequences, including increased costs to the insurance market. 81 Fed. Reg. at 31,376, 31,444.

But, despite admitting that it does not expect covered entities to maintain nondiscrimination protections for transgender people, HHS casts aside the commenters' concerns about ensuing health harms and claims, stating without support and contrary to the evidence in the administrative record, that denials of health care are "rare" and "based largely on unsubstantiated hypothetical scenarios." 85 Fed. Reg. at 37,191-92. This downplaying of the problem's severity is contrary to HHS's prior factual findings and the ample evidence in the administrative record showing widespread discrimination against transgender people in the health care context.[51] HHS's assertion that discrimination against this group is "rare" or "hypothetical" is contrary to the evidence before the agency, and is therefore arbitrary and capricious. *See N.Y.*, 414 F. Supp. 3d at 545 (citing *State Farm*, 463 U.S. at 52-53).

And while HHS had previously concluded that the 2016 Rule was necessary to comply with Section 1557's mandate to increase health care access to all, 81 Fed. Reg. at 31,459, HHS now claims it lacks data to evaluate the Rule's impact on the LGBTQ community. 85 Fed. Reg. at 37,182, 37,225. HHS's failure to consider the record evidence of harm resulting from

[51] *See generally* 80 Fed. Reg. 54,172; 81 Fed. Reg. at 31,376 (describing responses to 2013 RFI & 2015 NPRM); Ex. 75 (Collected Stories in Response to 2013 RFI); Ex. 76 (individual cmt. to 2013 RFI); *see also, e.g.*, Ex. 77, at 4-20 (Nat'l Ctr. for Transgender Equal. cmt.); Ex. 78, at 19-25 (Williams Inst. cmt.); Ex. 79, at 2 (NARAL Pro-Choice Or. Found. cmt.); Ex. 53, at 5-6 (Nat'l All. of State & Territorial AIDS Dirs. cmt.); Ex. 80, at 4-5 (Nat'l LGBTQ Task Force cmt.); Ex. 81, at 6-8 (Gender Justice cmt.); Ex. 82, at 12-16 (Whitman-Walker Health cmt.); Ex. 83, at 6-10 (Transgender Legal Def. & Educ. Fund cmt.).

discrimination that the 2020 Rule will ostensibly permit, or to make a reasonable inquiry into that harm, is arbitrary and capricious. *See Kern*, 284 F.3d at 1072. Separately, HHS asserts that complaints of discrimination based on transgender status—such as providers using unnecessary physical roughness or avoiding touching patients, intentionally concealing information about treatment options, and disclosing a patient's medical history without consent—should be redressed by state medical malpractice, tort, and battery laws. 85 Fed. Reg. at 37,191. If it is to fulfill its responsibility under the APA to consider both the benefits and costs of its regulations, HHS cannot simply dodge evidence of harm to transgender people and others by passing the issue off to state agencies and courts. *See Del. Dep't of Nat. Res. & Envtl. Control v. EPA*, 785 F.3d 1, 16 (D.C. Cir. 2015). Defendants' acknowledgement of these and other examples of discrimination against LGBTQ people belies their claim that they are unaware of such practices.

b. HHS failed to consider the harms to individuals' health and well-being from the removal of express nondiscrimination protections from the Rule.

The administrative record reflects many examples of transgender individuals being subjected to denial of treatment and coverage for health care, categorical coverage exclusions for gender-confirming health treatments, and inappropriate and humiliating comments from providers for being transgender.[52] For example, a transgender man recounted that his physician

[52] One transgender commenter was "laughed out of doctor's exam rooms, assigned the gender of 'it' while in the hospital, groped by health care providers trying to determine my 'real gender,' and denied insurance coverage for hormone therapy and anatomically appropriate preventive screenings." Ex. 84, at 1 (Baker cmt.). Another patient encountered a pharmacist who "refuse[d] to dispense my testosterone" after mischaracterizing transition medication as an "'off label use.'" Ex. 85, at 2 (Brush cmt.). A third transgender patient was denied care and medication, and "yelled at that I'm an abomination that deserves to die in front of a room full of waiting patients by the doctor." Ex. 86 (Cooper cmt.). Another patient was "forced to drop my pants at a doctors [sic] office to prove what genitals I had." Ex. 87 (anonymous cmt.). A mother and her non-binary child "experienced discrimination when seeking medical treatment simply because of the choice to use they/them pronouns." Ex. 88 (Olson cmt.). Another parent described being "faced with the scenario of potentially having to pay thousands of dollars out-of-pocket to cover" transition care for their child." Ex. 89 (Dominguez cmt.). A commenter also described a transgender coworker who suffered permanent brain damage after being denied hospitalization for a seizure. Ex. 90 (Cramer cmt.).

failed to inform him of a breast cancer diagnosis because the physician objected to his gender identity, resulting in needlessly delayed treatment.[53] Because of such experiences, people who experience discrimination in health care often postpone or do not seek needed care even if they are not denied care outright, as HHS previously recognized in the 2016 Rule. 81 Fed. Reg. at 31,444. HHS failed to meaningfully engage with these costs and consequences in the 2020 Rule.

Far from accounting for these harms, which HHS did in the 2016 Rule's cost-benefit analysis, the 2020 Rule summarily dismisses any such impact, and instead claims that HHS lacks data to evaluate how the Rule will impact transgender people and other members of the LGBTQ community. 85 Fed. Reg. at 37,225. HHS also claims it "lacks data or methods enabling it to provide quantitative estimates of any alleged economic impacts related to termination of pregnancy provisions" and refuses to calculate costs that would result from adopting Title IX's religious exemption. *Id.* at 37,239. Uncertainty as to the *magnitude* of harm to LGBTQ individuals and women is no excuse for disregarding a known effect of the Rule, particularly where there is ample evidence of harm in the record. *See Ctr. for Biological Diversity v. Zinke*, 900 F.3d 1053, 1075 (9th Cir. 2018); *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004); *Scalia*, 2020 WL 5370871, at *33 (vacating final rule that conceded harm might occur where agency attempted to rely on an "inability-to-quantify [harm] rationale" and failed to explain why estimate of harm in the administrative record was wrong).

HHS focuses solely on the alleged cost *savings* to HHS and covered entities from OCR's abdication of its obligation to investigate complaints of discrimination based on transgender status, gender nonconformity, and pregnancy termination, including savings from no longer processing or investigating gender identity discrimination complaints. 85 Fed. Reg. at 37,225,

[53] *See* Ex. 91, at 3 (Nat'l Ctr. for Transgender Equal. cmt.).

37,235-36. But HHS made no effort to consider, let alone quantify, the harms to individuals facing discrimination who can no longer file complaints or seek recourse from OCR. Nor did HHS make any effort to quantify the costs or benefits of refusing to accept complaints of sexual orientation discrimination, based on its erroneous view that such discrimination was not discrimination "on the basis of sex," despite *Bostock*'s holding to the contrary. Because refusing to quantify costs while relying on speculative benefits demonstrates unreasoned, results-oriented decision making that is impermissible under the APA, *see Mich.*, 576 U.S. at 73; *Am. Wild Horse Pres. Campaign*, 873 F.3d at 932; *Kern*, 284 F.3d at 1072, the Rule is arbitrary and capricious.

c. HHS also failed to consider or weigh public health costs and related harms to state and local governments.

Commenters also warned that the Rule will harm state and local governments.[54] HHS failed to contend with these concerns as well. For example, HHS dismissed comments expressing concern that the Rule would negatively affect public health and increase costs to states due to more people seeking care through government-funded programs; HHS's only response was that the "Department must follow the text of the ACA," 85 Fed. Reg. at 37,169, once again ignoring *Bostock* and other relevant precedent. Other commenters pointed out the additional enforcement burdens and costs to states that would result from increased discrimination complaints alleging discrimination based on sex stereotyping and gender identity, among other forms of sex discrimination. 85 Fed. Reg. at 37,240 (stating that OCR will now accept and investigate fewer sex discrimination complaints due to the Rule).

In response, HHS merely asserted that the States are unlikely to see an increase in complaints from transgender people because it had not enforced the gender identity protections

[54] *See e.g.*, Ex. 92 (cmt. from 22 states); Ex. 93 (City of New York cmt.); Ex. 94 (City of Oakland cmt.); Ex. 95 (Cal. Dep't of Ins. cmt.); Ex. 96 (Cal. Health & Human Servs. Agency cmt.).

of the 2016 Rule because of the *Franciscan Alliance* injunction. *See supra* at 9, 44. Based on its view that such discrimination was not covered, HHS did not otherwise attempt to consider the public health effects of its continued non-enforcement of these protections, or to engage with the many comments warning of those effects. An agency's failure to address comments identifying an important aspect of the problem is arbitrary and capricious, *see Del. Dep't of Nat. Res.*, 785 F.3d at 15-16, especially when it was based on an incorrect view of the law.

HHS's enforcement of Section 1557 for transgender complainants from the ACA's enactment in 2010 through the preliminary injunction in *Franciscan Alliance* in 2016 was based on a correct interpretation of the law that was ultimately vindicated by *Bostock*. Now, after *Bostock*, HHS is obligated to enforce Section 1557's sex discrimination protections on behalf of individuals alleging discrimination based on transgender status and sexual orientation. *See Bostock*, 140 S. Ct. at 1737. HHS's failure to consider the future harms of non-enforcement of these protections in light of this intervening case law was arbitrary and capricious.

B. The Rule's Elimination of Essential Language Access Protections Is Arbitrary and Capricious.

HHS's decision to weaken and in one case eliminate the robust language access protections of the 2016 Rule is also arbitrary and capricious because (a) HHS failed to justify its decision to replace the tailored "meaningful access" requirements of the 2016 Rule with those set forth in generally applicable federal guidance; (b) HHS failed to address its earlier factual findings, as well as record evidence, regarding the critical need for language assistance, notices, and taglines in the health care industry; and (c) HHS failed adequately to consider the human and monetary costs of leaving LEP individuals without any meaningful language access protections.

1. HHS failed to adequately justify its removal of the patient-centered "meaningful access" provisions of the 2016 Rule.

In the 2020 Rule, HHS weakened the "meaningful access" provisions of the 2016 Rule in two key ways, both of which erode Section 1557's protections for LEP individuals. First, the 2020 Rule dilutes the requirement that covered entities provide meaningful access to "each individual with limited English proficiency eligible to be served or likely to be encountered in its health programs and activities," 81 Fed. Reg. at 31,470 (former § 92.201(a)-(b)), requiring instead that covered entities provide such access to "[their] programs or activities by limited English proficient individuals" as an undifferentiated group. 85 Fed. Reg. at 37,245 (§ 92.101(a)). Second, the Rule removes the 2016 Rule's patient-centered test for compliance with the "meaningful access" provision, replacing it with a generic, four-factor test imported from other federal guidance. *See* 85 Fed. Reg. at 37,245 (§§ 92.101(b)(1)-(4)); 67 Fed. Reg. 41,455 (June 18, 2002) (Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons) ("DOJ LEP Guidance"); 68 Fed. Reg. 47,314 (Aug. 8, 2003) (Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons)) ("HHS LEP Guidance").

In making these changes, HHS asserts that the 2016 Rule conflicted with the DOJ LEP Guidance and the HHS LEP Guidance, and that the revisions are necessary to ensure consistency between Section 1557 and Title VI enforcement. *See, e.g.*, 85 Fed. Reg. at 37,210. That rationale, however, is inconsistent with HHS's earlier determination that the 2016 Rule complied with and codified the federal LEP guidance in the context of the ACA, *see* 81 Fed. Reg. at 31,453-54, and is based on no new factual findings.

Moreover, the standards imported from the DOJ LEP Guidance and HHS LEP Guidance are a poor fit for Section 1557. Indeed, as reflected in the 2020 Rule, the "meaningful access" standard treats LEP persons as a bloc, not as individuals; and the corresponding test for compliance instructs entities to balance the "number or proportion of [LEP] individuals eligible to be served or likely to be encountered in the eligible service population," "[t]he frequency with which LEP individuals come in contact with the entity's health program, activity or service," "[t]he nature and importance of the entity's health program, activity, or service" and "[t]he resources available to the entity and costs." 85 Fed. Reg. at 37,245 (§ 92.101(b)). The Rule, however, does not place any parameters on how those factors should be applied. *See id.* at 37,212, 37,245. Nor does the Rule actually require covered entities to provide language assistance services; instead, the Rule leaves it to each covered entity to apply the four-factor analysis and determine, on its own, whether it is obligated to offer any of the services listed in the Rule. *Id.* at 37,245 (§§ 92.101(b)(1)-(4)).

The 2016 Rule avoided this unlawful result by tailoring the long-standing principles of Title VI to the purpose and goals of the ACA. *See, e.g.*, 80 Fed. Reg. at 54,183; 81 Fed. Reg. at 31,410 & 31,453-54. It used a compliance test that both evaluated the nature and importance of the health program or activity and the particular communication at issue to the LEP individual; and took into account other relevant factors, including the existence of a written language access plan, the cost of language assistance service, and other resources available to the covered entity. 81 Fed. Reg. at 31,470 (§ 92.201(b)); *see* 81 Fed. Reg. at 31,416 (listing other relevant factors).[55]

[55] As HHS then explained, the 2016 Rule's compliance test "balances two core principles critical to effectuating Section 1557's prohibition on national origin discrimination": (1) that HHS "must 'ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English,'" and (2) that "the level, type and manner of language assistance services required . . . should be assessed based on the relevant facts, which may include the operations and capacity of the covered entity.'" 81 Fed. Reg. at 31,410. The 2020 Rule pays lip service to these principles, then abandons them.

By balancing the factors this way, the 2016 Rule prioritized patient needs to ensure that LEP persons can communicate effectively with their providers and insurers. *See, e.g.*, 80 Fed. Reg. at 54,183 (observing that "[t]he key to providing meaningful access for LEP persons is to ensure that the recipient/covered entity and LEP person can communicate effectively") (quoting 65 Fed. Reg. at 52,765). The 2020 Rule flips this approach on its head, prioritizing administrative costs over meaningful access, in conflict with Section 1557's purpose. *See* 80 Fed. Reg. 54,182.

2. HHS ignored the weight of the evidence and its own factual findings about the necessity of language access protections to combat national origin discrimination.

The 2020 Rule is also arbitrary and capricious because HHS disregarded its prior factual findings demonstrating the necessity of robust language assistance requirements to ensure meaningful access to health care for LEP individuals and ignored the weight of the record evidence that these requirements continue to be necessary. When promulgating the 2016 Rule, HHS credited evidence that LEP individuals face discrimination and other barriers to health care, with negative downstream consequences on individual health, community health care, and the distribution of health care resources. *See* 81 Fed. Reg. at 31,431, 31,459. As HHS found then:

> safe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other myriad purposes. This exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.

Id. at 31,431. HHS also determined that "reliable language assistance services" were necessary to combat this problem and thus implement Section 1557's prohibition against national origin discrimination. *Id.* To ensure that LEP individuals were made aware of their rights and could access health care with adequate language assistance services, HHS promulgated the robust notice, tagline, and language assistance requirements of the 2016 Rule. *Id.* at 31,398; *see* 80 Fed.

Reg. at 54,178 ("Apprising individuals of the availability of communication assistance under Section 1557 will promote both compliance with the law and better health outcomes.").

When HHS moved to repeal those protections a mere three years later, numerous commenters warned that the proposed changes would likely "result in a number of LEP individuals [being] unable to access healthcare, and will contribute to discrimination and to healthcare disparities for LEP individuals." 85 Fed. Reg. at 37,210.[56] In line with HHS's prior findings, commenters cautioned that such "increased discrimination in healthcare . . . would [in turn] lead people to delay or forego healthcare and would result in adverse health outcomes and greater overall healthcare costs to individuals," *id.* at 37,165, and that a "lack of understanding in a medical setting could cause harm and possibly death to patients with LEP," *id.* at 37,210. Other commenters noted that the 2016 Rule likely yielded benefits to the intended individuals. One entity identified a 28 percent reduction in "per-member per-month claims cost with its Spanish-speaking population" following its implementation of the rule's notice and tagline requirements. *See id.* at 37,233. The record also contains a study "finding that easily accessible language interpretation services avoided an estimated 119 readmissions that were associated with savings of $161,404 per month in an academic hospital." *Id.* at 37,234.

[56] *See, e.g.,* 85 Fed. Reg. at 37,165 (comments that "the proposed rule ignores the costs to individuals, especially LEP individuals, who will allegedly encounter additional barriers to healthcare as a result of the proposed change"); *id.* at 37,175 (comments that "the proposed changes . . . will lead to confusion among individuals and lead healthcare providers to discriminate based on race, color, and national origin" and "will result in LEP beneficiaries having less knowledge of available language assistance services"); *id.* at 37,204 (comments that removing language access protections "may result in decreased access to, and utilization of, healthcare by . . . people with LEP"); *id.* at 37,210 (comments that "this change will result in a number of LEP individuals unable to access healthcare, and will contribute to discrimination and to healthcare disparities for LEP individuals"); *id.* at 37,211 (comment that "informed consent is compromised when a language barrier prevents a patient from understanding what he or she is consenting to" and many others stated that "individuals with LEP face unique challenges in healthcare that are mitigated by language access services, and that the proposed rule might weaken access by patients with LEP to quality healthcare, resulting in patients' avoiding or postponing the medical care they require out of fear of discrimination or mistreatment due to their national origin or the language they speak"); *id.* at 37,212 (comment "that the proposed rule will adversely affect patient-provider dialogue in addiction treatment programs").

HHS dismisses this evidence and its earlier findings out of hand and merely contends—without any factual support—that the language access protections of the 2016 Rule were "unnecessary" and "confusing." *See id.* at 37,175-76, 37,204. As the record makes clear, however, the availability of language assistance services can be a matter of life or death for LEP patients; and those services, along with notice and tagline requirements eliminated from the 2020 Rule, led to cost savings. *See id.* at 37, 210, 37,233-34. Moreover, the "meaningful access" and compliance standards of the 2016 Rule comported with long-standing principles of Title VI, and many commenters urged HHS to keep them. *See id.* at 37,210. So too, the notice and tagline provisions were modeled after similar requirements in other statutes. 81 Fed. Reg. at 31,396.

HHS's failure to grapple with this reality—or otherwise provide factual support for its contention that these provisions proved "unnecessary" or "confusing"—renders its removal of these protections arbitrary and capricious.

3. HHS exclusively focused on the cost savings to covered entities, with no consideration of the likely individual and public health.

The 2020 Rule's failure to consider the necessity of robust language access protections renders the rule arbitrary and capricious in one other respect: it overlooks the harms that will flow from removing those protections, subordinating them to the administrative expenses of covered entities. In the 2016 Rule, HHS found that "when reliable language assistance services are utilized, patients experience treatment-related benefits, such as enhanced understanding of physician instruction, shared decision-making, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance," as well as additional "intangible benefits," and that "providers can more confidently make diagnoses, prescribe medications, reach treatment decisions, and ensure that treatment plans are

understood by patients." 81 Fed. Reg. at 31,459. Without those protections, HHS reasoned, LEP individuals may delay care or not seek it at all; and providers may face malpractice claims. *Id.*

Similarly, commenters to the 2019 NPRM alerted HHS that its proposed changes would result in the reduction of quality language access services; the avoidance of care by LEP persons; increased emergency room use; higher mortality rates; miscommunications between patients and providers about treatments and regiments, and resulting health harms; and increased malpractice costs, among others. 85 Fed. Reg. at 37,234. Commenters also pointed out that the NPRM would "lead to reduced awareness of language services by LEP persons and by the general public about their rights and protections." *Id.*

HHS acknowledged these harms in the 2020 Rule, but failed to address them in any meaningful way. *See* 85 Fed. Reg. at 37,234 ("The Department continues . . . to not be aware of a way to quantify [the] potential effects" of the likelihood that "repealing the notices and taglines may lead to persons not being made aware of their right to file complaints with OCR, and that some of those persons may suffer remediable grievances but will not complain to OCR absent notices informing them of the process"); *id.* at 37,325 ("The Department acknowledges the potential of reduced awareness of the availability of language services by LEP individuals made in this rule, or downstream effects on malpractice claims due to less awareness."). Instead, HHS sought cover in its view that LEP individuals are protected by *other* civil rights laws, and that the notice and tagline provisions led to unanticipated expenses for covered entities and information "overload" for English-proficient consumers. *See id.* at 37,176, 37,227-29, 37,233-34. That explanation, however, is unreasonable given the purpose of the ACA and the limitations of other laws in the health context, as well as the record evidence and earlier findings on the myriad harms accompanying the Rule's weakened language access protections.

C. The Rule's Incorporation of Title IX's Religious Exemption and "Abortion Neutrality" Provision Is Arbitrary and Capricious.

The 2020 Rule's incorporation of Title IX's broad religious exemption and "abortion neutrality" provision is arbitrary and capricious because HHS failed to consider two important aspects of the problem: (1) that these statutory exemptions, which specifically apply to educational institutions, are inappropriate in the health care context, and (2) the harms to individuals who will be denied health treatments, services, and insurance coverage because of these exemptions, particularly those for whom religiously-affiliated medical providers are the only available options, and attendant public health costs. *See State Farm*, 463 U.S. at 43. Furthermore, because HHS's incorporation of these provisions is at odds with its reasoned explanation in the 2016 Rule for why the incorporation of those provisions was dangerous, including that "a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results," *see* 81 Fed. Reg. at 31,380,[57] HHS's failure to provide a substantial justification for its policy reversal is arbitrary and capricious. *Encino Motorcars*, 136 S. Ct. at 2125-26. While HHS previously offered text- and evidence-based reasons for appropriately refusing to incorporate Title IX's blanket religious exemption and "abortion neutrality" provision in the 2016 Rule, 81 Fed. Reg. at 31,380, it fails in the 2020 Rule to plausibly explain why its earlier reasoning was wrong.

[57] *See, e.g.*, Ex. 97, at 9-10 (Nat'l Asian Pac. Women's Forum cmt.); Ex. 98, at 6-8 (NARAL Pro-Choice Am. cmt.); Ex. 99, at 10-13 (Nat'l Hispanic Leadership Agenda cmt.); Ex 53, at 10-11 (Nat'l All. of State & Territorial AIDS Dirs. cmt.); Ex. 100, at 4-10 (law and religion scholars cmt.); Ex. 101, at 12-14 (Am. Med. Student Ass'n cmt.); Ex. 102, at 3-4 (Ass'n of Am. Med. Colls. cmt.); Ex. 103, at 4-5 (Am. Acad. of Pediatrics & Soc'y for Adolescent Health & Med. cmt.); Ex. 81, at 8-10 (Gender Justice cmt.); Ex. 63, at 9-10 (HIV Health Care Access Working Grp. cmt.); Ex. 59, at 8-11 (Nat'l Latina Inst. for Reprod. Health); Ex. 104, at 14-16 (Planned Parenthood cmt.).

First, HHS did not rebut its earlier reasoning that, unlike parents or students voluntarily choosing religious schools, patients seeking health care often have no choice but to obtain such care from religiously-affiliated entities. 81 Fed. Reg. at 31,380. The 2020 Rule does not address the life-threatening consequences of health care discrimination, which, as HHS explained in the 2016 Rule, are not at issue in the school context. *Id.* Notably, HHS did not consider how, given the substantial evidence that religiously-affiliated hospitals and providers are becoming increasingly common, especially in rural areas, *see id.*,[58] a broad religious exemption authorizing those entities to deny care for discriminatory reasons is justifiable or consistent with the ACA's statutory purpose of expanding access to care. With respect to the abortion neutrality provision, HHS now claims it "lacks data or methods enabling it to provide quantitative estimates of any alleged economic impacts related to termination of pregnancy provisions" and refuses to consider any such harm. 85 Fed. Reg. at 37,239. But HHS cannot simply bury its head in the sand and ignore the consequences of its actions. *See Am. Wild Horse Pres. Campaign*, 873 F.3d at 932; *Kern*, 284 F.3d at 1072. Rather, because HHS is not dealing with a "blank slate," HHS must reckon with its prior findings and provide the requisite "detailed justification" for its policy reversal. *Fox*, 556 U.S. at 515. For these reasons, HHS's failure to consider the harms from exempting religiously-affiliated health programs from Section 1557 is arbitrary and capricious.

Second, HHS does not explain its departure from its earlier, textually-supported position that neither Section 1557 specifically, nor the ACA generally, contain or authorize the incorporation of religious exemptions. 81 Fed. Reg. at 31,380. While HHS contends that "Section 1557 incorporates the statutory scope of Title IX, so it is appropriate for this rule to

[58] *See, e.g.*, Ex. 105, at 8-9, 15, 16 & n.3 (Ctr. for Am. Progress cmt.); Ex. 106, at 6-9 (Human Rights Watch cmt.); Ex. 105, at 13-14 (Planned Parenthood cmt.); Ex. 59, at 10-11 (Nat'l Inst. for Latina Reprod. Health cmt.); Ex. 71, at 16-17 & n.91 (Lambda Legal cmt.); Ex. 107, at 16-17 (Nat'l Inst. for Reprod. Health cmt.); Ex. 108, at 4 (Maine Family Planning cmt.); Ex. 109, at 4 & n.13 (Am. Psychiatric Ass'n cmt.)

incorporate the Title IX statutory language concerning religious institutions and abortion neutrality," 85 Fed. Reg. at 37,207-08, Section 1557 incorporates only Title IX's protected classifications and enforcement mechanisms, *see supra* at 4-5, so HHS's justification fails.

HHS also failed to account for its prior determination that these exemptions would delay or deny medically necessary care—including in emergency circumstances—because of discrimination. *See* 81 Fed. Reg. at 31,380. As HHS found in 2016, these exemptions will especially harm people who may "have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions." *Id*. Indeed, at "no point did the agency even assert that a religious exemption would preserve meaningful access to health care for vulnerable populations — let alone provide evidence supporting any such conclusion." *Whitman-Walker*, 2020 WL 5232076, at *28. HHS's new assertion that the "religious exemption will ensure 'high-quality and conscientious care,' 85 Fed. Reg. at 37,206," is "a 'conclusory statement[]' . . . delivered entirely without elaboration or support." *Id.* (quoting *Getty v. Fed. Sav. & Loan Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1987)). Indeed, HHS failed even to acknowledge "the more likely outcome of patients' being *denied* care" or address the impact of such exemptions on access to health care in underserved communities. *Id.* This failure to engage in reasoned decision-making renders the incorporation of Title IX's religious exemption and "abortion neutrality" provision to be arbitrary and capricious. *See id.*

CONCLUSION

For the reasons above, the 2020 Rule violates the APA. Accordingly, the Court should grant Plaintiffs' Motion for Partial Summary Judgment, enter judgment in their favor, and vacate the 2020 Rule in its entirety.

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Respectfully submitted,

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